

**UNIVERSITY of the WESTERN CAPE**

**FACULTY OF LAW**

**BENEFIT SHARING FROM TRADITIONAL KNOWLEDGE AND  
INTELLECTUAL PROPERTY RIGHTS IN AFRICA : “*An Analysis of  
International Regulations*”**

**STUDENT NAME: John S. Ombella**

**STUDENT NO: 2674985**

**DEGREE: LL.M (International Trade and Investment Law in Africa)**

**SUPERVISOR: Mr. John E. Hunt**



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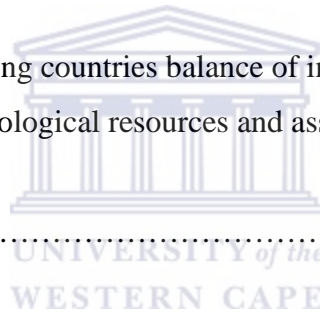
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## **ABRIVIATIONS**

WIPO-World Intellectual Property Organization.

TRIPS-Trade and Related aspects of Intellectual property Rights

CBD-Convention on Biodiversity

WTO-World Trade Organization

TK-Traditional Knowledge

DC-Developed Countries

DVC- Developing Countries

LDC-Least Developing Countries

IPL- Intellectual Property Law

IPR- Intellectual Property Rights

TKB- Traditional Knowledge Based



## **Overview of Chapters**

### **Chapter One**

Chapter one covers an introduction and the background of the problem. It tells the reader the nature of the problem and the scope of the research

### **Chapter Two**

Chapter two deal with theoretical framework of genetic resources and the associated TK. It addresses the need to protect TK in local African societies from being pirated by the western research institutions and corporations.

### **Chapter Three**

Chapter three provides the reader with the critical analysis of the international regulations dealing with TK and benefit sharing. This analysis forms the basis of the need of effective domestic regulations in individual countries, as will be discussed in details in the next chapter.

### **Chapter Four**

Chapter four deals with the analysis of the domestic regulations in selected African countries. This chapter will provide an in depth study of domestic regulations hence it will reveal to the reader how effective or not these regulations are, in curbing the problem under research.

### **Chapter Five**

This is a concluding chapter. It will provide for the observations, recommendations to be adhered as a solution of the problem under research so as the local community can enjoy their benefit sharing. Lastly it will provide concluding remarks in winding up the thesis.

DECLARATION

I John Sebastian Ombella declare that, this thesis is my own work except where acknowledged in the text.

Signed .....

John S. Ombella

(Student)

Dated on this .....day of .....2007



## CERTIFICATION

I certify that, I have read and hereby recommend for acceptance by the University of the Western Cape the thesis entitled; **BENEFIT SHARING FROM TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY RIGHTS IN AFRICA: "An Analysis of International Regulations,"** submitted in partial fulfilment of requirement of LL.M Degree of the University of the Western Cape.

Signed .....

Mr. John E. Hunt

Supervisor

Dated on this..... day of ..... 2007





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## **DEDICATION**

This work is dedicated to my Father Sebastian Sinato Ombella and mother Catherine d/o L.M. Msaki. They brought me up, sent me to school and taught me the right way of life, believing in God and hold education for my liberation. Really they mean and count a lot in my life and always they will.

Stay in blessings forever more.



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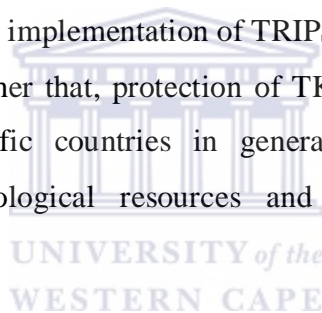
To all thank you so much and the Most high has blessed you for that.

## ABSTRACT

This thesis is written in the contemplation of the idea that, it is only through protection of the Traditional Knowledge (TK) in African Local societies where then these societies can rip the benefit of its commercialization and non-commercialization.

It is thus centered on the emphasis that, while the African Countries are still insisting on the need to have amendments done to the TRIPS Agreement, they should also establish regulations in their domestic laws to protect TK from being pirated. This emphasis is mainly raised at this time first due to the wide spread of bio-piracy in African Local Societies by the Western Multinational Pharmaceutical Corporations.

Also, it is a reaction against the perception held by most African Countries that, having no regulation protecting TK may be used as a negotiation tool in multilateral, or it may help them to extend the time for implementation of TRIPS Agreement. This paper present the humble idea of the researcher that, protection of TK is for the good of the African local societies and the specific countries in general especially in this world of commercialization of the biological resources and development in science and technology.



## CHAPTER ONE

### 1.0 INTRODUCTION AND BACKGROUND TO THE RESEARCH

African societies are not only blessed to have vast unexploited natural resources, for example in the form of gold, fuel and forest materials, but they are also rich in knowledge and genetic resources that can be used to tackle a number of current global and regional health problems<sup>1</sup>. It is perhaps paradoxical that most of these genetic resources and associated knowledge base is found in the poorer communities which are relatively powerless from the political and economic context.<sup>2</sup>

It can be argued that, if there is to be regulation on how to access and use such resources, then, it is the communities from which the resources originates which should derive a tangible benefit. As a result of the existence and availability of a rich traditional knowledge based, the pharmaceutical corporations and research institutions from developed countries sometimes venture into such communities where they appropriate various kinds of knowledge and associated genetic resources in order to commercialize knowledge. This works to the financial detriment of such societies<sup>3</sup> and those persons who are the repositories of such intellectual property knowledge base.

Despite the fact that the African societies managed to fight against the colonial exploitation of natural resources and the colonial imposition of European based systems

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<sup>1</sup> Gerard Bodeker 'Indigenous Medical Knowledge, The law and Politics of Protection', Green Collage, University of Oxford, (2000) where he argues that, majority of the population of most non-industrialized countries still relies on traditional forms of medicines for every day health care. In many countries, up to 80-90% of the population is in this category. Medicinal plants and to a lesser but important extent animal products, form the material medica of this tradition. See also Vandana Shiva, *Captive minds, captive Lives*, RFSNRP, New Delhi, (1995) p 128, where it is stated that, Millions of housewives, birth attendants and herbal healers carry on village based healthy tradition. Seventy percent of health care needs in India are still based on traditional systems based on the use of medical plants.

<sup>2</sup> Dawnes R.D and Sarha A Larid, *Community Registries of Biodiversity-Related Knowledge: The Role of Intellectual property in Managing Access and Benefit*. UNCTAD Biotrade Initiative (1999) pg 1

<sup>3</sup> Ironically, one can even say that, now the table has turn, as we experience a reverse transfer of technology in which it is the poor developing countries that are transferring knowledge and thus technology to the rich developed world. For further discussion see also, Martin Khor, (2003) *IPRs and Biodiversity: Stop the Theft of Indigenous Knowledge*, [http:// www.twinside.org.sg/title2/briefing\\_papers/Noo07.pdf](http://www.twinside.org.sg/title2/briefing_papers/Noo07.pdf) (accessed August 5<sup>th</sup>/ 2006)

of rule, the exploitation of traditional knowledge based (TKB) is still persisting in a surreptitious or covert manner that is not easily perceived by most developing societies. This form of subtle exploitation does not leave a physical trace or even attract public outcry, as it is the case with other environmental problems such as deforestation.

“Bio-piracy as 'a silent disease'. It is hardly detectable, it frequently does not leave traces and is an elusive activity perpetrated and often abetted by many well-known multinational companies. 'Unfortunately, it does not attract the same media coverage or public outcry as other environmental problems, such as deforestation and pollutant emissions. But this silent pillage is robbing developing countries in Africa, Latin America and Asia of the means to finance important sustainable development projects, and is a powerful disincentive for their biodiversity conservation efforts’<sup>4</sup>.

This work examined whether the current intellectual property rights (IPRs) under the international regulations such as the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), and the Convention on Biodiversity (CBD) and domestic regulations in selected African countries provide sufficient protection of the traditional knowledge (TK) base associated with genetic resources as utilized in medical treatment in local African Societies.

The research was mainly carried out to address the fact that, African societies have been suffering from the exploitation of their existing genetic resources and their associated TK by the western multinational pharmaceutical corporations<sup>5</sup>. This was so, despite the presence of the international regulations governing the IPRs. The main cause of this

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<sup>4</sup> See, the views of the current Brazilian ambassador in London, Jose Mauricio Bustani, when he interviewed by the Observer newspapers of London on bio-piracy, <http://www.gurdian.co.uk/science/story//o.htm>, and <http://www.timesnews.co.ke/29aug06/business/buns1.html> (accessed 4<sup>th</sup>/December 2006)

<sup>5</sup> Jay McGown Out of Africa: Mysteries of Access and Benefit Sharing, Edmonds Institute and African Center for Biosafety (2006) [www.edmonds-institute.org](http://www.edmonds-institute.org) (accessed 30<sup>th</sup> October 2006)

phenomenon is the growing need for biodiversity as a source of medical advances in addressing the emerging health problems in the world.<sup>6</sup>

Traditional societies that still hold their values and ways of life have a great deal to contribute to current global thinking in addressing the emerging health problems through resorting to and commercializing local medicines and then modifying them with the benefit of current scientific methodologies. For commercial purposes African role-players may well need to enter into joint ventures with the appropriate western pharmaceutical corporations.

“There is a growing international interest in the potential application of know how that indigenous people and rural communities have developed and applied to natural resources over generations. The problem here is that, the TK and practices are being accessed by non-indigenous individuals, public and both private researchers and, companies in both industrialized and developing countries for commercial purposes to the detriment of the local communities.”<sup>7</sup>

The further aim of this research was to explore the question whether these international and local regulations have addressed sufficiently the problem of bio-piracy in most African local societies. That is whether they have provided strict rules regulating IPR so as to protect the interest of the traditional African societies. Such rules may include invoking:

- 1) The provision for proof in the governing contract of benefit sharing,
- 2) A disclosure of the origin of the genetic materials used in the invention seeking protection under the TRIPS.<sup>8</sup>

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<sup>6</sup> Caroline Lase'n Di'az (2005) Intellectual Property Rights and Biological Resources: An overview of Key Issues and Current Debates, Foundation for International Environmental law and Development London, states that; A 199 study provided estimates of the size of global markets for uses of genetic resources in the pharmaceutical, seed, cosmetics, horticultural and Botanical Medicine Industries with figures ranging from US\$20billion a year in the horticultural sector, to US\$300billion a year in the pharmaceuticals. See also, Ten Kate K and Laird S, (1999) The commercial use of Biodiversity, Earthscan, London

<sup>7</sup> Ibid

<sup>8</sup> For a long time the African countries and other least developed countries have put forward this proposal but they have faced an opposition from the western Countries.

Despite the fact that African countries and other developing countries have raised the alarm on the need to have the international regulations (TRIPS) amended,<sup>9</sup> yet in their proposals, they have not given the minimum standards of what should amount to benefit sharing<sup>10</sup>. Commissions and inquiries<sup>11</sup> have also been established in various jurisdictions to deal with the problem at hand and their suggestions were all geared towards the concept of benefit sharing and regulation of access to the genetic resources by the relevant authorities in a given country.

For example, John Voumard (2000), the chair of the Commonwealth Public Inquiry into Access to Biological resources in Commonwealth Areas had also commented on the need of protection of TK in efforts to realize the benefit sharing. The inquiry had, the terms of reference directing them to focus on equitable sharing of benefits arising from utilization of TK, innovations and practices in commonwealth countries. To comment on benefit sharing the chair had the following;

“I have listened carefully to the concerns of traditional owners in Commonwealth areas, particularly about the misuse of their knowledge of biodiversity. This issue has also been the subject of many submissions and representations. This Inquiry has sought to come to terms with the limitations of the existing legal system in protecting and valuing this knowledge. I believe the best protection presently available for the rights of Indigenous peoples to their biological resources and their intellectual property can be achieved through

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<sup>9</sup> Graham Dutfield, TRIPS-Related Aspects of Traditional Knowledge, International law, (2001) Vol. 33:233 “...Developing country Government increasingly complain about TK piracy by transnational (usually US based) corporations, and has added this to their list of reasons to be dissatisfied with TRIPS. Several developing country governments have gone so far as to submit official proposals to both organizations (WIPO and WTO)... fro measures to be taken to protect TK legally and to prevent its miss appropriation by industry through inappropriate use of patents ...” pg 237

<sup>10</sup> The effect of this will be seen in the next chapter where we will see the complexities associated with the issue of benefit sharing. It will be seen that, the local society are always forgotten, and wherever remembered they are being marginalized with other stakeholders in contract of benefit sharing. See also the Developing Countries Propose TRIPS amendments to curb Bio-piracy, available at, [http://www.CENTAD.ORG/TRADENEWS74.ASP:\(accessed December 1<sup>st</sup> / 2006\)](http://www.CENTAD.ORG/TRADENEWS74.ASP:(accessed December 1<sup>st</sup> / 2006))

<sup>11</sup> These commissions includes The UK Government Commission on Intellectual Property Rights, Commission on IPR Country case study, Institutional issues for Developing Countries, Policy making, Administration and Enforcement, Inquiry



inclusion of appropriate contractual terms. The solutions the Inquiry recommends are practical and, most importantly I believe, empowering for Indigenous communities that have leased their land to the Commonwealth.”<sup>12</sup>

This work also examined the effects of giving a state sovereignty over the genetic resources. This is a viewpoint, which is in opposition to the most commonly held and traditional approach, which regarded biological and genetic resources as being a common heritage of humankind, and, therefore freely available to all.<sup>13</sup> It is this trend that the law seems to ignore. The TK that may be associated with biological genetic resources, and sometimes this knowledge need not be and is not in public domain. It may be owned by a particular individual in a given society<sup>14</sup>.

The fundamental question posed by this thesis was, does the international regulations provide an equitable remedy to these individuals in circumstance where the IPR is wrongfully appropriated? This is an important consideration because the gaps existing in international regulations may have been the cause of some of the problems encountered by the local African societies in their efforts to curb the wide spread misappropriation which have to date generally been unsuccessful.

In addressing the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (seventh session) one of the participants had the following to say,

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<sup>12</sup> See, Voumard J, Commonwealth Public Inquiry into Access to Biological Resources In Commonwealth Areas, EnvironmentAustralia, Canberra, 2000, <http://www.ea.gov.au/biodiversity/science/access/inquiry/index.html>, the same is also cited by Matthew Rimmer, in his article, Legal Protection of Indigenous Traditional Knowledge and Cultural expressions: Blame it on Rio: Biodiscovery, Native title and Traditional knowledge

<sup>13</sup> See, the Preamble of the CBD Convention which accord State sovereignty on the Biological resources, thus, states are recognized as owners of the biological resources hence, any access and use of the same shall be in accordance to the rules and regulations of the said states.

<sup>14</sup> Graham Dutfield, TRIPS-Related Aspects of Traditional Knowledge, Case W. Res. J. International law (2001) Vol. 33:233, where he says that, the presumptions that TK is always in a public domain is false and its widely acceptance may have negative implications on the peoples in the local communities ([in African Societies] emphasis added), pg 238

“Gaps in the international property system had also been identified as the critical element in misappropriation. However none of the legal tools suggested...address the problem involved the use of patent or other intellectual property rules.”<sup>15</sup>

As shown above, there is likelihood for gaps in the applicable international regulations. Such possibility demands that there should be domestic regulations in African countries to remedy the situation. The question is how many African Countries have in place the relevant regulations governing access to genetic resources? How effective or detailed these regulations are in protection against plunder of the genetic resources and the associated traditional knowledge? These questions are answered in this research in order to determine how far TK is protected in African countries for the betterment of the local societies.

From the above analysis it is apparent that the need of African traditional societies in their own countries to protect TK against bio-piracy exists. There are a number of ways through which the TK in relation to medical treatment can be protected. TRIPS, for example allows for the *sui generis*<sup>16</sup> approach for the member countries of WTO to protect plant and animals in their own domestic legal system.

*Sui generis* has no uniform meaning. However it is used to denote alternative rights regimes for the protection of community innovations that are not protect-able under conventional intellectual property laws, and, in an even broader perspective, for systems embodying farmers' or indigenous peoples' rights<sup>17</sup>. In this context therefore, it seems to

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<sup>15</sup> See, Report on the Seventh Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in November 2004, Geneva available at [www.wipo.org](http://www.wipo.org) See also issue No. 7 raised in Intergovernmental Committee on Intellectual Property and Genetic Resources, TK and Folklore: 10<sup>th</sup> Session Geneva November 30<sup>th</sup> –December 8<sup>th</sup>, 2006 [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_10/wipo\\_grtkf\\_ic\\_10\\_3.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_10/wipo_grtkf_ic_10_3.pdf) accessed 30th December 2006

<sup>16</sup> See article 27 (3)(b)

<sup>17</sup> Dan Leskien and Michael Flitner, The TRIPS Agreement and Intellectual Property Rights for Plant Varieties (1998) <http://www.grain.org/briefings/?id=177> (accessed 15<sup>th</sup> February 2007)

be a very good approach adopted by the TRIPS agreement as the local communities in protecting their medicinal plants and TKB can use various approaches that suit their conditions.

Sui generis allows the member states to adopt any protection,<sup>18</sup> which will be in its favor in protecting animals and plants that are the most used in medical treatment by the traditional societies. For example, India has developed the TK digital libraries,<sup>19</sup> which shall contain the lists of all TK's held in India. This will facilitate the work of Patent granting authorities by providing information on the availability of the specified TK against which, patent can not be granted. This approach will protect both the TK and the medicinal plants in the sense that, no patent shall be granted in detriment of the local community.

It is questionable whether the African traditional societies, which have not protected TK domestically, can challenge the registration of the patent in circumstances where patent ignores the TKB. These patents may either be held in international or local registries in developed countries.<sup>20</sup>

There are a number of problems facing the African traditional societies in attempting to protect TK. Such challenges will be addressed as set out below. It should be born in mind that, most African countries have signed the Convention on Biodiversity.<sup>21</sup> However, the same convention does not deal with the issue of bio-piracy that occurred prior to that convention coming into force. That is, it has no retrospective effects.

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<sup>18</sup> Article 27 (3) (b) of TRIPS agreement provides for options on protection of plant varieties either by patent, or by sui generis or combination of both.

<sup>19</sup> See, R. A Mashelkar, *Intellectual Property Rights and The Third World*, Council of Scientific and Industrial Research, New Delhi

<sup>20</sup> Most of patent in pharmaceuticals are being registered with either EPO or USPTO trace their origin in African traditional societies, see also *Out of Africa: Mysteries of Access and Benefit Sharing*, <http://www.edmounds-institute.org>, (accessed 5<sup>th</sup>/August/2006)

<sup>21</sup> See annexure 'A' on page 13 showing the list of about 39 African countries who are signatories to the Convention on Biodiversity.

Furthermore, countries engaged in high level of bio-piracy are not signatories to the convention. Even where they are signatories they have not ratified the convention and its provisions cannot be enforced. For example; the US government signed the convention in 1992 but was not ratified by the senate since then to date.<sup>22</sup> This existing situation plus many other reasons such as:

- 1) Lack of information about the fact that patents held by some corporations trace their origin to African countries,
- 2) A lack of an efficient legal institutional framework to deal with bio-piracy.
- 3) Financial difficulties as well may obstruct African Traditional societies from protecting TK in the manner to be recognized internationally.
- 4) Non-disclosure of information from the traditional healers<sup>23</sup>

### **1.1 STATEMENT OF THE PROBLEM**

The problem was the continued use of TK from African local societies by the western pharmaceutical corporations for commercial purposes, without benefiting the local community who are the owners and the custodians. This problem is worse especially in African countries where the current IP regulations, both international and domestic do not address this problem adequately.<sup>24</sup>

This problem exposes the African local societies to being exploited by the developed countries. The exploitation takes place in both intellectual wealthy and the genetic resources used in medications. This is due to the scientific and technological advancement and capabilities to engage in research as opposed to developing African countries. This is very possible due to the weakness in the current international IP

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<sup>22</sup> Jeremy Lovell, Biodiversity and the Global crisis, 05 May 2004. <http://www.bionet-us.org/> accessed 16<sup>th</sup> February 2007

<sup>23</sup> See, F K Mpanju (Patent examiner ARIPO), ARIPO's Initiative on Traditional Knowledge and Access and Benefit Sharing, a workshop held in Cape Town on 19<sup>th</sup>-24<sup>th</sup> November 2006.

<sup>24</sup> See, An International Seminar on Systems of Protection of Traditional Knowledge was jointly organized in New Delhi by India and UNCTAD during 3-5 April, 2002. pg 11

regulations as and the lack of tight domestic rules or regulations in protection of the TK and associated knowledge.<sup>25</sup>

The international and domestic intellectual property regulations and polices does not provide an answer to solving the problem of bio-piracy. Bio-piracy commonly takes place in developing countries by persons and corporation from the developed countries. Thus these regulations do not assure equal and fair benefit sharing that ought to have arisen from the access and use of the genetic resources and TKB.

The standpoint adopted in this work was that, TK needs to be well protected both domestically and internationally to assure the realization of benefit sharing between its users and the holders. This can be achieved through inter alia;

- a) Establishing the tight domestic rules/regulations.<sup>26</sup> These regulations have to be backed up with the necessary legal institutional frameworks on access and use of the genetic materials in these African local societies;
- b) Amending the IP rules and regulations in these African local societies at the national level to reflect the needs under the rules on access and use of the TK;
- c) Amendments of the TRIPS Agreement to include the proposals given by the developing countries (Africa inclusive) to avoid the continuing wide-spread of bio-piracy in these societies;
- d) Lastly, challenging the already pirated genetic resources and associated TK in view of making sure that the respective local societies will benefit out of it.

## **1.2 HYPOTHESIS**

The aim of this work was to explore the question, whether the international and local IPR regulations have addressed sufficiently the problem of bio-piracy in most African local societies.

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<sup>25</sup> The current IP regulation (TRIPS) at international level is biased towards the western scientific knowledge, as it does not recognize the TK.

<sup>26</sup> These regulations need to provide a minimum benefit sharing below where by the users of TK will not be allowed to give the local societies in African countries. This will help to assure fair benefit sharing between the users who are always the corporations from developed countries with giant capital and highly skilled in negotiations as compared to the locals who are the holders of the TK.

### **1.3 OBJECTIVES OF THE RESEARCH**

This work examined the effectiveness of the current international and domestic intellectual property regulations in addressing the problem of bio-piracy in local communities in African countries.

Another objective of this research was to explore the extent of protection of TK in selected developing countries. It is argued that, despite the fact that the developing countries are proposing for protection of TK at international level, they may be doing nothing (or very little) domestically to avoid or prohibit bio-piracy<sup>27</sup>.

Moreover, this research endeavored to examine the possible challenges that local African societies faces in addressing the problem of bio-piracy. Lastly the researcher will give recommendations on how to enhance protection so as to achieve the goal of equal and fair benefit sharing.

### **1.4 METHODOLOGY**

This research was conducted in analyzing the international IPR regulations TRIPS and CBD. Also an analysis of the selected domestic regulations and policies in some African local societies will be carried. Preferably, South Africa and Tanzania are the countries chosen by the researcher due to the following reasons:

- i) South Africa is a developed country in comparison with its counterpart Tanzania. This presupposes the fact that, its regulations and policies are a bit advanced in addressing the problem at hand. It can be said therefore that, South African regulations can be used as a model in comparison to what their fellow African countries has done.

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<sup>27</sup> Graham Dutfield, (2001) TRIPS-Related Aspects of Traditional Knowledge, International law Vol. 33:233, where he argues that, many developing country governments have made determined efforts to promote TK protection as a TRIPS –related issue, even while they generally do very little about TK at their national level... pg 239

- ii) Tanzania is a least developed country, which needs to have such regulations in place by learning from fellow African country subjected under the same threats of bio-piracy.

Questionnaires were also issued in academic Institutions, which deal with the research in local/traditional medicines.<sup>28</sup>

Lastly, a thorough study of the existing literatures in the subject of IPRs, as far as they are related to the use of TK was carried out in various libraries and Internet.

### **1.6 Target Population and sample**

The targeted populations were the academic institutions, which deal with the research in local/traditional medicines in South Africa and Tanzania.

### **1.5 SCOPE OF THE STUDY**

The research tried to survey the relevant international and domestic intellectual property regulations and policies in African countries. This was aimed to examine both the international and domestic IPR regulation in African combat the problem of bio-piracy.

A comparative study was carried between two countries that were taken as the study of this research, these were; South Africa and Tanzania due to the above stated reasons.<sup>29</sup>

It is only by fighting against bio-piracy when the local society can be assured of equal and fair benefit sharing in the utilization of genetic resources and TK.

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<sup>28</sup> See, The South African Herbal Science and Medicine Institute (SAHSMI) found in University of the Western Cape, and any other institutions carrying out the same activities.

<sup>29</sup> Some few references may be done in other jurisdictions in developing countries where the problem of bio-piracy has been dealt with, example India.

## CHAPTER TWO

### 2.0 MEANING OF TRADITIONAL KNOWLEDGE AND THE NEED FOR ITS PROTECTION

#### 2.1 Meaning of TK

Every society in the world has its own ways of life distinct from the other. Such distinction varies from the language used by its people, the ways of dressing and even their social interactions. It also includes the way its people interact with environment surrounding them in realization of their daily needs. For example: food, shelter, medicine to cure their daily illness and many more.

The knowledge derived from the long time experience, use of the environment surrounding man has a lot of value in the modern society. This knowledge gathered in all sphere of life and being transmitted from one generation to another in an informal way, is generally referred as Traditional Knowledge (TK)<sup>30</sup>.

Traditional Knowledge (TK) is that (knowledge) which is held by members of distinct culture and/or sometimes acquired by means of inquiry peculiar to that culture and concerning the culture itself or the local environment in which it exist<sup>31</sup>. The nature of the knowledge is also diverse: it covers, for example, literary, artistic or scientific works, song, dance, medical treatments and practices and agricultural technologies and techniques<sup>32</sup>.

However, one may argue that, even the western societies may have their own traditional ways of life. There exist a major distinction between the TK and the western knowledge.

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<sup>30</sup> This term is defined by the CBD Convention to mean the Knowledge, innovations and practices of indigenous and local communities embodying traditional life styles, as provided in note 2 of article 8(j) of the Convention on Biological Diversity.

<sup>31</sup> See, J.Mugabe, P. Kameri-Mbote et al. (2001-5) TRADITIONAL KNOWLEDGE, GENETIC RESOURCES AND INTELLECTUAL PROPERTY PROTECTION: Towards a New International regime, IELRC Working Paper, available at, <http://www.ielrc.org/content/w0105pdf>

<sup>32</sup> See, UK Commission on Traditional Knowledge, chapter 4; Traditional Knowledge and Geographical Indications.



The distinction is based on the ways through which TK is generated, recorded and transmitted from generation to generations<sup>33</sup>.

It should also be born in mind that, when we refer to the term ‘Tradition’ it does not mean that the knowledge does not involve an inventive step. Had this been the case then the traditional society would not have a justification in their efforts against bio-piracy. To justify that TK involves an inventive step, the term “traditional” as used in TK is interpreted to mean, the way it is acquired and used.

In other words, the social process of learning and sharing knowledge, which is unique to each indigenous, culture, lies at the very heart of its ‘traditionalism’. Much of this knowledge is actually quite new, but it has social meaning and legal character, entirely unlike the knowledge indigenous peoples acquire from settlers and industrialized societies<sup>34</sup>.

To complement on the above statement, TK is said to be the information that people in a given community based on experience and adaptation to a local culture and environment have developed over time and continue to develop. This knowledge is used to sustain the community and its culture and maintain the genetic resources necessary for the continued survival of the community<sup>35</sup>.

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<sup>33</sup>See, Martha Johnson, Research on Traditional Environmental Knowledge: Its development and its Role, as cited by Graham Dutfield (2001) TRIPS-Related Aspects of Traditional Knowledge (supra) pg 241 where he enlisted the distinctions of Traditional Environmental Knowledge from the Western Scientific knowledge as the former being transmitted thorough oral traditions, learned through experience, being based on the understanding that the elements of matter have a life force, based on data generated by resources users, it is mainly qualitative (where as western is mainly quantitative), it is holistic and intuitive in its mode of thinking (where as western science is analytical), also it is rooted in a social context that sees the world in terms of social and spiritual relations between all life forms and it derives its explanations of environmental phenomena from cumulative, collective and often spiritual experiences. See also, Vandana Siva (1996), “Protecting Our Biological and Intellectual Heritage”, as cited in Peter Darhos (1999) International Library of Essays in Law &Legal Theory Intellectual Property, Queen Mary and Westfield Collage, University of London, pg 149, See also, Coenraad J. Visser; MAKING INTELLECTUAL PROPERTY LAWS WORK FOR TRADITIONAL KNOWLEDGE in J. Michael Finger and P. Schuler (Ed) (2004) Poor People’s Knowledge: Promoting Intellectual Property in Developing Countries, pg 210

<sup>34</sup> See, Russel Lawrence Brush Indigenous Knowledge and Biodiversity, as cited by Graham Dutfield (2001) TRIPS-Related Aspects of Traditional Knowledge (supra) pg 242

<sup>35</sup> See, Hansen, Stephen, et al (2005) Traditional Knowledge and Intellectual Property: A Hand book on Issues and options for Traditional Knowledge holders in Protecting Their IP and Maintain Biological Diversity, Washington DC, Pg 3

Examples of TK;

- i) The use of Hoodia cactus by the Bushmen in Africa to stave off hunger when they were going for long hunting activities.
- ii) The use of tumeric in India for healing wounds, the use of plao-noi in Thailand for treatment of ulcers<sup>36</sup>.
- iii) Another one includes the use of Maytenus buchanii from Shimba Hills of Kenya, used by Digo to cure cancerous conditions<sup>37</sup>.

This research is centered on the idea that, to assure that the African local societies benefit from their TK, they need to protect it in various ways against any form of appropriation. However, TK in the current IPR regime seems to be a burning issue due to the nature of the existing system in IPRs. That is TK seems not to be recognized and thus not protected by the existing system.

This is mainly based on the facts that, in practice the two are related but the later is not regulated under the existing international and some domestic IPR regime. Example, patent may be granted to protect IPRs in a medical product where by its origin is founded on TK.

However, it is worth to know the nature and origin of IPR, before analyzing whether it protects TK or not.

## **2.1 IPRs AS PRIVATE PROPERTY**

The concept underlying intellectual property rights (IPR) is that, they are granted to an individual as a private property. Example, when patent or copyright is granted to an applicant, be it a corporation or a natural person, it excludes the rest of the society members from claiming on the same any right in a given limited period of time in accordance with the granting authority.

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<sup>36</sup> Ibid pg 3-4

<sup>37</sup> See, John Mugabe (1999) Intellectual Property Protection and Traditional Knowledge: An Exploration in International Policy Discourse, Nairobi Kenya, pg 6

The concept of private property has its genesis in developed countries especially the first countries to undergo industrialization, England being one. The era of agrarian revolution in England was characterized with one major economical approach, enclosure system<sup>38</sup>.

Thus, the more land one could have enclosed and utilize would have entitled him an exclusive ownership plus its proceeds from the rest of the community members. Despite the fact that the system helped England in agrarian revolution by allowing expansion of productive possibilities<sup>39</sup>, yet it has its set backs as it is argued that,

“Enclosure was not merely unjust in itself but harmful in its consequences. It was a cause of economic inequality crimes and social dislocation... Among some of the harms/ injustices caused by the enclosure system was...the convention of the free holders into peasants, seasonal wage laborers, other harms were difficult to classify, for example the loss of form of life, disruption of traditional social relations and even the relationship of human being to the environment... “<sup>40</sup>

Intellectual property Rights on the other hand reflects the true picture of the development of the concept of private property from real or tangible properties to the intangible ones<sup>41</sup>

Vandana Shiva,<sup>42</sup> had also commented on enclosure of biodiversity by the current International IPRs Regulations where he says,

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<sup>38</sup> This was the system applied by the farmers during Agrarian Revolution in England where by they enclosed the fertile land and used it for cultivation and hence avoid a scatted farming which did not gave them many yields at the end of the year.

<sup>39</sup> This occurred due to the transfer of inefficiently managed common land into the hands of a single owner who could use it for effective production, it also created incentives for large scale investment allowed control over exploitation, and in general the resources would be used efficiently. Unless the landlord new the fruits of his labor would be his alone, he would not have invested in drainage scheme, purchase of sheep, or the rotation of crops in order to increase the yields of his acreage.

<sup>40</sup> Agostino A and Ashton Glenn, (2006) A Patented World? Privatization of Life and Knowledge, Fanele, Johannesburg, pg 20

<sup>41</sup> ‘...once again, things that were formerly thought to be uncommodifiable, essentially common, or outside the market altogether are being turned into private possession under a new kind of property regime. But this time the property in question is intangible, existing in database, business methods and gene sequences...(Agustino A supra)

<sup>42</sup> Vandana Shiva, (2001) Protect or Plunder? Understanding Intellectual Property Rights, Penguin Books India (P) Ltd, pp 44-45

“The enclosure of biodiversity and knowledge is the final step in a series of enclosures that began with the rise of colonialism. Land and forests were the first resources to be enclosed and converted from commons to commodities. Later, water resources were enclosed through dams, ground water, and mining and privatization schemes. Now it is the turn of biodiversity and knowledge to be enclosed through IPRs.”

### **2.3 Meaning of IPR and the need to protect TK in the current IPR system**

Intellectual property rights refer to the legal rights, which result from intellectual activity in the industrial, scientific, literary and artistic fields. In short it can be said to mean that IPRs are particular aspects of property covering all things, which emanate from the exercise of human brain<sup>43</sup>.

International organizations such as world intellectual property organization (WIPO) and countries have laws to protect intellectual property generally for two main reasons;

- 1) To give legal expression to the moral and economic rights of creators in their creations and such rights of the public in access to those creations.
- 2) To promote, creativity and the dissemination and application of its results and to encourage (competition) fair-trading, which would contribute to economic and social development in the world generally<sup>44</sup>.

IPRs grants rights to the owner, to produce the product, sell, even use of the same in exclusion of others, in a given period of time<sup>45</sup>. Historically, IPRs such as patent has been justified on either consequentiality or deontological grounds. As pointed out by Graham

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<sup>43</sup> See, Ian Walden, Preserving Biodiversity: the role of property rights; in Intellectual Property Rights and Biodiversity Conservation: An interdisciplinary analysis of values of medicinal Plants, (1998) Edited by Timothy M. Swanson p 181

<sup>44</sup> Samuel Wangwe, et al Institutional Issues for Developing countries IP Policy making, administration and enforcement- Tanzania, Economic and Social Research Foundation.  
<http://www.iprcommission.org/papers/text/studypapers> accessed on 18/09/06

<sup>45</sup> See, Caroline T Owoseni (2001) International Conference on Intellectual Property, Internet, Electronic Commerce and Traditional Knowledge: Challenges in the Protection Intellectual Property Rights (IPRs); A Nigerian Perspective, pp 2-3

Dutfield,<sup>46</sup> the consequentialist justification is that when inventors, authors, or artists, have an exclusive rights, to produce and sell their works, society benefits. This proposition is based on two assumptions.

- First, it assumes that such a right encourages inventors to invent and authors to write.
- Second, it presupposes that, the greater the quantity of invention and creative works released into the public domain, the more the public benefit through economic or cultural enrichment or greater physical well-being.

Thus, generally IPRs are rewards for inventors and artists for their contributions to the public good or that they are incentives that encourage creative endeavor. The deontological arguments are derived from consideration of rightness and wrongness.

For instance, it may be argued that using somebody's invention or creative work without his or her permission is morally wrong, because it is in some way harmful to that person or because it is a means of unjust enrichment

The most recognized and regulated IPRs under TRIPS can traditionally be divided into two branches, Industrial Property and Copyright.

Industrial Property, which includes inventions (Patents)<sup>47</sup>, Trademarks<sup>48</sup>, Industrial designs<sup>49</sup>, Geographic indications of source<sup>50</sup>; and Copyright<sup>51</sup>, which includes Literary and Artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

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<sup>46</sup> Graham Dutfield (200) Intellectual Property Rights, Trade and Biodiversity, Earthscan Publications Ltd, London, pp 18

<sup>47</sup> See Article 27

<sup>48</sup> See Article 15

<sup>49</sup> See Article 25

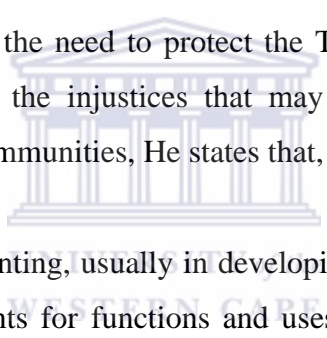
<sup>50</sup> See Article 22

<sup>51</sup> See Article 9 that govern Copyrights and related rights.

Among the existing IPRs, patent is the commonest approach used by the Pharmaceutical Corporation from developed countries in pirating the genetic resources and the associated TK from the local communities.

A number of authors have written on the need to protect TK in the developing world against the piracy. Piracy takes place by transforming TK into scientific knowledge experimented in laboratories; thereafter by using patent it thus acquire a different status. The status of such a knowledge once found in public domain change to that of a private right owned by an individual or a corporation. This approach is opposed to the former situation, where the right was owned by the indigenous society or an individual in the society.

Martin Khor<sup>52</sup> has pointed out the need to protect the TK and the genetic resources in Indigenous society. He shows the injustices that may be caused by lack of such a protection, to the indigenous communities, He states that,



“the problem is the patenting, usually in developing countries, of ingredients and other substances of plants for functions and uses that have already been in the public domain and in practice for many years or generations. In many cases, these are plants or substances that have been used in developing countries. Similarly, protection (Including through patenting) in the developed countries is being granted for plant varieties, the origin of whose genetic materials are in developing countries”

The above statement firstly, shows the appropriation of the valuable resources and the associated knowledge in developing countries by the developed countries.

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<sup>52</sup> IPRs and Biodiversity: Stop the Theft of Indigenous Knowledge (2003), available at, <http://www.twinside.org.sg>, visited on, August 5<sup>th</sup>/2006

Secondly, it also shows how the developed countries use the existing international IPRs regulations in benefiting themselves from the developing countries.

The author went on exposing the number of injustices that the local community will undergo when the developed countries have pirated the genetic resources and associated TK from them.

Among the said injustices include;

- a) Firstly, the appropriation by corporations' of local communities' knowledge on biodiversity use transfers away the rights of the communities' and become the private and monopoly rights of these institutions. The IP holders can make monopoly profits through commercializing the patented products, while the local communities that either developed or used the knowledge usually do not get any of the benefits.
- b) Secondly, and even more ironic situation arises if the patented process or product leads to the sale of products at higher prices to developing countries from where the patented process or product originated.
- c) Thirdly, the patent owners from the developed countries can apply for similar patents in developing countries from where the knowledge originated. The local communities in the developing countries concerned would thus be constrained from making use of the patented process or making or selling the patented product.
- d) Another injustice that could occur is that, the patenting of biological resources can restrict or prevent producers from using the processes and products relating to traditional knowledge.

For example, a corporation that has successfully applied for patent over the use of a plant for certain functions (for instance, to treat some ailments) could attempt to prevent others

from using the plant for the same functions. Those who have been keeping and using Traditional knowledge could thus be restricted and discouraged.<sup>53</sup>

This will have negative effects to the society on issues of access to medicine. The genetic resources will be highly needed by these pharmaceutical corporations hence the society will be denied their right to use it. Moreover, the situation will be worsened where the patent holder will protect its products in the country where the genetic resources were found. This is because the most corporations are always selling the drugs at a high price that is not affordable by these local societies.<sup>54</sup>

It is from the above likely injustices that may be encountered by the local societies in developing countries, where the researcher was inspired to examine whether the existing international and domestic IPRs regulations address the problem of bio-piracy in African local societies by the said corporations.

According to McGowns' findings of cases that are suggestive of Biopiracy, "*Out of Africa: Mysteries of Access and Benefits Sharing*"<sup>55</sup> It shows that the African local societies still suffer from bio-piracy.

This problem is a result of the acts of the corporations in developed countries patenting drugs irrespective of the fact that the drugs trace their origin in local societies in Africa. Worse enough these corporations had nothing in return for the use of genetic resources and the associated knowledge to these local societies.

Among the countries mentioned to have been affected by bio-piracy in this report include Kenya, Namibia, Mauritius, South Africa, Angola, Botswana, Ethiopia and neighboring countries, Egypt, Congo (Brazzaville) and Central and West Africa<sup>56</sup>.

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<sup>53</sup> IPRs and Biodiversity: Stop the Theft of Indigenous Knowledge (2003), pg 2, available at, <http://www.twinside.org.sg>, visited on August 5<sup>th</sup>/2006

<sup>54</sup> These drugs may be the result of the use of genetic resources and TK from the same local societies in African countries.

<sup>55</sup> Available at <http://www.edmunds-institute.org> visited on August 5<sup>th</sup> /2006



In summary, this report exposes and condemns the appropriation of the African genetic resources by the corporations in developed countries. It went further showing that it is not only the biodiversity in medicinal plants but also in other sectors. It is stated that,

“When you look at what has been taken in the recent past from Egypt to South Africa, it runs the gamut (range) from biodiversity used for medicines to biodiversity for agriculture, horticulture, cosmetics, and industrial purposes. It is unbelievable how much has been taken without a public accounting and probably without any permission from the communities and peoples involved...<sup>57</sup>”

Moreover, the report tries to establish how hard the local societies in developing countries can find it to prove the case of bio-piracy. This is so, despite the fact that bio-piracy is widely spread in Africa. This happens especially where the African local societies have no any law or regulations governing access to the genetic resources and the TK associated to it.<sup>58</sup> The situation shows the need to have TK protected in both international and domestic level for the local societies to benefit from it.

A famous writer on Biodiversity issues, Vandana Shiva analyzed<sup>59</sup> two paradigms existing in two groups who are all interested in biodiversity. These groups are the local societies whose survivals and sustenance is directly linked to the local biodiversity

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<sup>56</sup> Ibid, See, Chee Yorke Hoeng (2006) New Report points to widespread Biopiracy in Africa, available at, [http://biosafety-info.net/file\\_dir/16176166044226dd411185.doc](http://biosafety-info.net/file_dir/16176166044226dd411185.doc) visited on August 5th /2006

<sup>57</sup> See Mariam Mayet (Executive Director of the African Centre for Biosafety) as quoted by Chee Y. Hoeng in his article cited above

<sup>58</sup> See the comments by the Edmunds Institute President/director Beth Burrows as cited by Chee Y. Hoeng, where he said; “It’s not easy to prove bio-piracy. Where contracts (benefit sharing contracts between the local societies and the foreign user of the genetic resources and associated knowledge.) are not published and national rules of access and benefit sharing may not exist or are not attended to by bio-prospectors, or the companies and institutions they represent, it is difficult to verify claims of theft, even when you catch the thieves with the booty in hand...or in their patent portfolios...”

<sup>59</sup> See Drahos Peter (1999) The International Library of Essays in Law& Legal Theory, Second Series; Intellectual Property, Dartmouth Publishing Company Ltd, England, pp 141-143

utilization and conservation, example, the use of herbal medicines in carrying on village healthy tradition (or even spiritual well being).<sup>60</sup>

Another group is formed of the commercial interests whose profits are linked to utilization of global biodiversity for production of inputs, into large scale, homogeneous, uniform, centralized, and global production systems. It represents the group that view biodiversity as merely raw materials for the production of commodities and for maximization of profits.

The views of the later group represent the corporations from the developed world. These corporations engage themselves in pirating the genetic resources and associated knowledge from the developing countries for maximization of profit through patent.

The patents granted to these corporations are in ignorance of obvious knowledge and practices of these local societies in African countries. This shows a need to have clear regulations, and legal institutional framework in both international and local spheres in curbing the problem of bio-piracy.

The need of effective protection of TK against the pirating corporations is much more needed especially in this world of scientific and technological development in developed countries. This is because, apart from the said corporation pirating the biological resources, it is possible today to bring out new products or find out new use of existing products based on TK utilizing the technological developments in the field of biotechnology.<sup>61</sup>

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<sup>60</sup> See also Darshan Shankar, (1994) Medicinal Plants and Biodiversity Conservation, in Biodiversity Conservation: Whose Resource? Whose Knowledge ed. Vandana Shiva, INTACH, New Delhi.

<sup>61</sup>It is argued that, "...The development of new technology and the new use of traditional knowledge based products today is the major threat to the survival of many of these communities. The modern cultural industries as well as the manufacturing industries now commercially exploit the traditional knowledge based products using new technology without the permission and sharing of profits with the communities. It is possible today to bring out new products or find out new use of existing products based on traditional knowledge utilizing the technological developments in the field of biotechnology.

African local societies having no sufficient scientific development are thus subjected to the problem of bio-piracy. The western corporations will thus go on appropriating due to either loose or no regulations in access and use of the genetic resources and TK in these societies.

The corporations in developed countries use a number of ways to exploit the genetic resources in Africa local societies. Such ways include researchers of traditional medicine who arrive in the indigenous areas as tourists to find out how local people cure certain illnesses.

These "tourists" then take the remedies to the developed countries and patent them as though they were their own inventions. It is also noted that, most of the developing countries do not protect the indigenous people and farmers from cultural pillaging and many governments see the indigenous peoples' complaints as science fiction.<sup>62</sup>

Although, the idea on the reluctance of the developing countries in recognizing the need to protect the biological resources and the associated TK may be time barred taking into account that time has passed and the issue of biopiracy is now a burning issue in developing countries.<sup>63</sup> However in the year 2000, the Union of B.C. Indian Chiefs hosted a conference on Protecting Knowledge: Traditional Resource Rights in the New

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This is proved beyond doubt particularly in the field of medicines, agriculture etc. The bio- prospecting help the scientists in the modern pharmaceutical research laboratories to get the know how to develop new products or new use of existing products.... the development of new products or new use of existing products enable the industries to get protection for these products through the formal intellectual property laws..."see, Traditional Knowledge–The changing Scenario In India, available at, <http://www.edu.ac.uk/ahrb/publications/online/varkey.htm> visited on October 9th/2006.

<sup>62</sup> See, Antensio Lopez, Kuna Indigenous Leader who runs an International Campaign against 'the stealing of genes from native people' in Panama, in his article titled; Indigenous People raise alarms about... available at, <http://www.netlink.del/Zeitung/97129b.htm> visited on August 5th /2006

<sup>63</sup> This is because the article was written in December 19<sup>th</sup>/ 1997, the situation seems to have changed since some countries like India and South Africa has regulations dealing with Biodiversity and associated knowledge

Millennium<sup>64</sup> where still we see the comments rose by the participants on the need to protect the TK in the local communities in developing world.

In this conference one of the participants<sup>65</sup>, when asked to comment on the need of the colonized people to protect and renew their culture and traditions even if only a fraction remains, had the following to say;

“as long as their heritage survives in the memories and hearts of their elders, there is still hope to recover what seems to be lost...But it is also true that a people can lose its heritage in a single generation if they neither respect nor value that heritage”

It is obvious that, the only way to show respect and value to the heritage in generations is to protect it. Protection will assure the sustainable, equitable and fair use of the same for the benefit of the society. When asked to comment in the context of defending traditional resources rights, the participant stated that;

[in the] “new world of international economic cooperation, trade liberalization, and privatization,” institutions like the WTO, corporations, and financial institutions are “gaining greater power and assuming the functions of the nation-state.” These entities are vulnerable to consumer actions, public opinion, and investment trends and tools to defend traditional resource rights should be able to “reach directly into the conscience and into the pockets of private and non-governmental sectors.”

Graham Dutfield in his paper<sup>66</sup> had also pointed out the need to protect TK in developing countries where he was analysing the national systems to protect TK in some selected

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<sup>64</sup> See, <http://www.ubcic.bc.ca/protect.htm> visited on September 18<sup>th</sup>-2006

<sup>65</sup>The Chair of the UN Working Group on Indigenous Peoples. Who also is a 1993 recipient of the UN’s Human Rights Award.

<sup>66</sup>See, Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences of Selected Developing Countries, available at, [http://r\(\).unctad.org/trade\\_env/docs/dutfieldpdf](http://r().unctad.org/trade_env/docs/dutfieldpdf) visited on December 18<sup>th</sup> 2006.

countries in Latin America. He argues that, developing countries do not regulate TK in their domestic regulations due to two main probable reasons.

- a) Firstly, they probably would like to use it as a negotiating tool in multilateral trade issues.
- b) Secondly, they would like more preferential treatment in implementation of TRIPS Agreement.

The second reason is based on the facts that, they will be given more time to enact the relevant regulations and probably financial and technical support in doing the same. However it is the considered view of the researcher that, such reasons are jeopardising the rights of these countries in benefiting out of biodiversity and the associated TK, which is being taken by the western corporations.

The main concern of protection may also be based on the cultural decay due to the increasingly globalization. This had a negative effects on the TK associated with the cultures which are dying due to a great influence from other cultures as the effects of the world being a village. It is said that,

“cultures are dying out faster than the people associated with them. It has been estimated that, half of the worlds’ language-the storehouses of people’s intellectual heritage and the framework for their unique understanding of life will disappear within a century...<sup>67</sup>”

It is also noted that, among other things that accelerates the dying of culture and hence shows an emergent need to protect the existing TK are; genocide, uncontrolled frontier aggression, military intimidation, extension of government control, unjust land policies, cultural modification policies, and inappropriate conservation management<sup>68</sup>.

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<sup>67</sup> See, Inter-Commission Task Force on Indigenous Peoples (1997), as cited by Graham Dutfield (2000) Developing and Implementing National Systems For Protecting Traditional Knowledge: A Review of Experiences of Selected Developing Countries, pg 5

<sup>68</sup> Ibid

All the factors above affects the biodiversity, hence has a negative implication on TK as well. African countries are also subjected under the same threats to TK, thus they need to take measures to protect their TK for the betterment of its holders.

In one of the conference<sup>69</sup> one of the participants stressed the need of regulations to protect the traditional knowledge when he was presenting on the protection of Traditional knowledge and folklore he stated as follows;

“protection of traditional knowledge has become a mainstream issue, and is necessary as no satisfactory system of protection exists at present. One threat to traditional knowledge is its unauthorized commercial use, without any sharing of the ensuing benefits with traditional custodians and communities...”

Protection of TK is against piracy in African societies is of capital importance due to the nature of the biodiversity that is always associated with the knowledge itself. Although African countries have boundaries, the nature of the biodiversity is always not determined by the existing country's' boundaries.

However, one had to know what it mean by protecting TK. Is it that the TK should be protected against piracy (in the sense that whenever used the holders get the benefits directly accruing from the use) or it should be protected in the sense that it should not be commercialized at all? Still there is a conflict of the nature of protection of TK.

On one hand, some indigenous people and traditional communities want a positive protection that is; they want to benefit from the commercialization of TK. On the other

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<sup>69</sup> The Conference on the Commission on Intellectual Property Rights: How Intellectual Property Rights could Work better for Developing countries and Poor People, held in Royal Society in London in 2002., See also, <http://www.iisd.ca/linkages/sd/SDIPR/> Visited on October 2006

hand some members of these group and communities are concerned with the cultural, social and psychological harm caused by the authorized use of TK<sup>70</sup>.

It is the viewpoint of this research that, it is through protection of TK against piracy where by local societies can, either use it for commercial realization of benefits or decide to use it for their social and psychological satisfaction in exclusion of others<sup>71</sup>.

It is from the above view where one sees a need to raise awareness of the most of the developing countries on the need to have the special international and domestic regulations governing the access and use of the genetic resources and associated TK for their own benefit.

## **2.1 RELATIONSHIP BETWEEN TK AND GENETIC RESOURCES:**

Before addressing the issue of bio-piracy, it's worthwhile to know the relationship existing between the TK and the biological or genetic resources. On face of it, TK is a knowledge just like any other knowledge acquired in formal ways, thus it qualify to be a subject of protection under the IP regulations just like any other knowledge.

However, it may form a kind of exception with other form of knowledge in the sense that, it is generally not owned individually but rather the community in which it develops. TK develops and reshapes itself perpetually as the society adopts itself into the changing environment, hence any attempt to protect it under the current IP regulations, which have a specific period of protection, might affect this knowledge.

The relation existing between TK and the genetic resources has its basis on the fact that man has to use his knowledge to benefit out of the environment he is surrounded with for his food, medicinal plants and animals or even microorganisms. Hanns Ullrich in his

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<sup>70</sup> See, J.Michael, Finger &P. Schuler (2004) POOR PEOPLE'S KNOWLEDGE: Promoting Intellectual Property In Developing Countries, World Bank and Oxford University Press, Washington, pp 12

<sup>71</sup> Professor Ajeet Mathur, in his article titled, **WHO OWNS TRADITIONAL KNOWLEDGE?** Argues that, communities and countries, rich in bio-diversity and knowledge of traditional medicine, may gain if they are able to share in trade and investment that arise from the global development of the healthcare industry.

paper<sup>72</sup> pointed out that, biodiversity related traditional knowledge may have a value of its own, and being knowledge promise of its protection may be sought under the rules of intellectual property or by analogy to these rules. He also pointed out that, in general, the biodiversity related knowledge derives its value from genetic resources to which it applies.

TK is the intangible part of the genetic resources. The two are inseparable in the sense that the value accorded to the genetic resources found its basis in the knowledge that the genetic resources worthy it. It is argued that, traditional knowledge is generally associated with biological resources and is invariably an intangible component of such a biological resource.

TK has the potential of being translated into commercial benefits by providing clues for development of useful practices and processes for the benefits of mankind. The valuable leads or clues provided by TK save time, money and investment of modern biotech and other industries into any research and product development<sup>73</sup>.

So much as the relation between genetic resources and TK has been established to be inseparable. It is at this point one can see the genuineness of the complaint of local/traditional societies about the issue of bio-piracy. Its effects are depriving both the material and knowledge from local societies, while benefiting the corporations in developed countries. However, it is worth to know what bio-piracy means at this juncture before the discussion went further

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<sup>72</sup> Traditional Knowledge Biodiversity, Benefit-Sharing and Patent System: Romantics v. Economics (2005) European University Institute, Italy pp 6-7

<sup>73</sup> See Elizabeth Varkey, Traditional Knowledge –The Changing Scenario in India, available at, <http://www.law.edu.ac.uk/ahrb/publications/outline/varkey.htm>, visited on October 9<sup>th</sup>-2006



## 2.2 MEANING OF BIO-PIRACY AND ITS JUSTIFICATION IN AFRICAN SOCIETIES:

The word bio-piracy is a blend of two words, which are *bio* and *piracy*. The first term, *bio* means concerning living things<sup>74</sup>, while the second one, *piracy* mean illegal copying and sale of books, tapes, videos etc<sup>75</sup>.

However, the list in the second meaning is not exhaustive. It suggests one thing that is, the illegal copying and selling of intangible assets. This is the knowledge associated in the books and even the tapes and videos and many more. Bio-piracy has been defined in a number of ways although ultimately it conveys the same meaning having the same elements in these definitions. Some of the elements can be seen in the following definitions;

That, bio-piracy refers to the appropriation, generally by means of patents, of indigenous biomedical knowledge by foreign entities (including corporations, Universities and governments) without compensatory payment<sup>76</sup>.

Vandana Shiva defines bio-piracy to mean, the use of intellectual property systems to legalize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures.<sup>77</sup>

It is also referred to as the acquisition of biodiversity, i.e., biological material (plants, animals, microorganism, and their parts), or of TK related to that biodiversity, without

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<sup>74</sup> See Longman Dictionary of Contemporary English: The complete Guide to Written and Spoken English New Edition. P112

<sup>75</sup> Ibid pg 1069

<sup>76</sup> See, Meaning of Biopiracy available at, <http://en.wikipedia.org/wiki/Biopiracy> accessed on September 5th 2006

<sup>77</sup> Shiva Vandana, (2001) Protect or Plunder: Understanding Intellectual Property Rights, University Press Ltd. Bangladesh pg 49

the prior informed consent of those whose biodiversity or traditional knowledge has been taken<sup>78</sup>.

From the definitions above it's obviously seen that, the term biodiversity may be said to have three elements, which are;

- ◆ The act of Appropriation (mostly by means of patents)
- ◆ Subject matter of appropriation (mostly has to do with the medicinal genetic resources and associated TK<sup>79</sup>)
- ◆ That there is no any compensation made to these societies, (owners and custodians of the said genetic materials and TK).

Examples that justify bio-piracy in African local societies are as follows;

The first can be seen from the cactus plant called Hoodia in Southern parts of Africa a tradition being practiced by the Bushmen (San people). Hoodia is a succulent plant that grows throughout the semi-arid areas of Southern Africa. The San have traditionally used Hoodia stems to stave off hunger and thirst when on long journeys, as it acts as an appetite suppressant. Now, a British company who say it will become a best-selling slimming drug has patented the active ingredient in Hoodia<sup>80</sup>.

The idea that the plant can be used to develop a best-selling slimming drug is founded on the traditional knowledge and the long time experience held by the Bushmen. The British company, which has patented the drug arising out of the use of hoodia did not, first of all obtain the prior informed consent of the Bushmen on the use of their TK, and it did not compensate them in any way for the use of their TK<sup>81</sup>.

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<sup>78</sup> See, Chee Yoke Heong, New report points to widespread bio-piracy in Africa, available at, [http://biosafety.info.net/file\\_dir/166.doc](http://biosafety.info.net/file_dir/166.doc), visited on August 5th 2006

<sup>79</sup> However this definition may be very narrow in the sense that it consider biomedical resources only and ignore other, but it is worth while to note here that the subject matter of appropriation under bio-piracy may include non medical genetic resources such as the Basmati rice in India

<sup>80</sup> See, Stolen Knowledge: Article about the Hoodia Kaktus, available at, <http://www.evb.ch/en/p5html> visited on 17th-December 2006, see also, Antony Burnett 'In Africa the Hoodia Cactus keeps men alive. Now its secrets is stolen to make us thin' The Observer, Sunday June 2001

<sup>81</sup> However, it should be known that, the Bushmen community challenged the patent and they managed to get a share of the royalties arising out of the sale of the said drugs. (Although it is always being cited as an example of unfair benefit sharing as will be seen later)

Another good example of Bio piracy is the use of *Maytenus buchananii* from Shimba Hills in Kenya by National Cancer Institute (NCI) of US, used by Digo to cure cancerous conditions<sup>82</sup>

Other examples of possible misappropriation in African local societies include a recent report issued by Jay McGown<sup>83</sup> include the treatment for diabetes, from Libya and Egypt, the patent is being held by the Phytopharm Plc, Co. in UK, but there is no evidence of benefit sharing related to this patent neither is there any policy governing the issues of associated traditional knowledge.

More over the antifungal from a Giraffes' dung originating from Namibia, Merck & Co. a giant pharmaceutical is holding patent although there is no any evidence of benefit sharing.

From Ethiopia there are about four medicinal plants that have also been patented in US, although there is no evidence of benefit sharing between the holders of the patent and the societies where the plants originated.

It can be noted that, most of the given examples above did not talk much or clearly about the TK as it is on the case of hoodia and *Maytenus buchananii*. The main reason being, the African local societies who are the owners and custodian of the same might have not got this information. Therefore, the US patent office had granted patent to the applicant in ignorance if the fact that what actually is being patented is not novel.

It is questionable why bio-piracy is taking place in these local societies by the corporations from the developed countries. This is so despite the fact that, we have the rules and regulations that govern the IP at international level. The regulations provide the

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<sup>82</sup> See, John Mugabe (1999) Intellectual Property Protection and Traditional Knowledge: An Exploration in International Policy Discourse, Nairobi, Kenya pg 6.

<sup>83</sup> Jay McGown, (2006) Out of Africa Mysteries of Access and Benefit Sharing, Edmonds Institute in Collaboration with African Center Biosafety.

minimum requirements to be achieved for the any patent applicant before patent is granted to him. In addressing this doubts, Vandana Shiva is of the view that,

“bio-piracy and intellectual piracy in which western commercial interests claim products and innovations derived from and currently used by indigenous knowledge traditions as their intellectual property protected through intellectual property rights like patents has emerged as a results of the devaluation and hence the invisibility of indigenous system of knowledge and the lack of protection for these system...western style IPR systems are biased towards western knowledge systems which reduce biodiversity to its chemical or genetic structures, the indigenous systems get no protection, but piracy of these system is protected.”<sup>84</sup>

The continued appropriation of genetic resources and associated TK shows that still the western countries are exploiting African society to date. It is obvious that the western societies still undermine our continent through their jurisprudence in the multilateral trade system where African states are members as well. Professor J.A Ekpere<sup>85</sup> is of the view that, African societies need to adopt uniform rules in defeating the developed countries from exploiting them.

“The further development of this legislation<sup>86</sup> at the national level provides the challenging opportunity to reflect and recognize Africa’s cultural heritage in the laws of the modern national state. It provides a chance for Africa to throw off the colonial yoke of western jurisprudence (law making) and develop one that most fully reflects its wealth of cultural perspectives and inherently respectful

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<sup>84</sup> See Vandana Shiva, *Protecting Our Biological and Intellectual Heritage*, in Peter Darhos (1999) *The International Library of Essays in Law &Legal Theory: Intellectual Property*, Dartmouth Publishing Co. Ltd, pg 149.

<sup>85</sup> The Project Coordinator, the Organization of African Unity; Scientific, Technical and Research Commission. Nigeria.

<sup>86</sup> The OAU Model Law, *The protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological resources*.

relationship with the diverse biological world with which its cultures have co-evolved”<sup>87</sup>

## **Conclusion**

It is worthwhile to conclude that, African local societies need to benefit out of their TK once used. The main way to realize this goal is through raising awareness in African communities on the need to protect their TK. Protection of TK should be firstly, in their domestic regulations and secondly, holding their efforts in trying to strike the balance between TK and the western IPR regime at the international level.

This will help them in achieving their goal of protecting the TK and realizing sustainable use, equal and fair benefit sharing between the user and the holder of TK. This is because; there are complex issues that have negative effects to the African local societies on benefit sharing agreements. These issues will be resolved if there will be domestic regulations protecting TK and guiding the benefit sharing to these societies. The next immediate chapter will address this complexity in detail.

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<sup>87</sup> See, J.A Ekpere, The OAU Model Law, The protection of the Rights of Local Communities; Farmers and Breeders, and for the Regulation of Access to Biological resources: Explanatory Booklet, OAU, Scientific, Technical and Research Commission. Lagos.

## CHAPTER THREE

### 3.0 THE CURRENT PROTECTION OF TRADITIONAL KNOWLEDGE AT INTERNATIONAL LEVEL

The issue to be addressed in this chapter is whether the current international intellectual property rights regulation (IPRsR) and policies provide protection of TK associated with resources used in medications?

The most common branch of IPRs that will be discussed under this chapter will be the Patent system. This is the most notoriously used by the corporations in developed countries in plundering the genetic resources and TK from the local societies in developing countries.

To begin with the Conventions that deals with TK and IPRs, CBD Convention, is the only convention which directly tries to protect TK<sup>88</sup> among its member states at International level. It establishes some requirements such as;

- i) Prior Informed Consent of the holders of TK;
- ii) equal and fair benefit sharing arising from the utilization of such knowledge, innovations and practices<sup>89</sup>.

TRIPS Agreement on the other hand did not in anyhow make reference to the TK in its provisions. Despite the fact that it was signed after the CBD convention<sup>90</sup> where one would have expected to see the issue of TK being addressed clearly in the latter convention as it was dealing with trade issues.

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<sup>88</sup> Despite the fact that it does not define TK but rather referring to the knowledge, innovations and practices of indigenous and local communities, embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, which should be promoted for wider application.

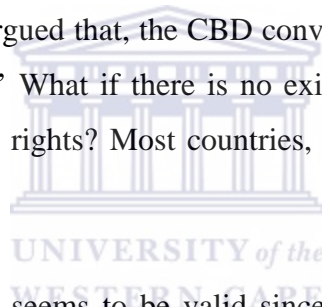
<sup>89</sup> See Article 8 (j) of the CBD Text.

<sup>90</sup> CBD Convention was signed in 1992 in Rio De Janeiro, while TRIPS Agreement came into force in 1995 as a result of Uruguay Round

However, the provisions that provide for requirements to be fulfilled by patent applicants seem to have adverse effects on the issue of TK. The CBD Convention as seen above would have been of help but its worth to note here that the Convention is not part of WTO Agreements hence it binds only the member states.

More over, despite the fact that CBD convention has provided for the requirements in accessing and using the TK, yet it has its own weakness that makes it not suitable in guaranteeing TK protection especially in individual countries. This is due to the fact that, the convention gave the state the sovereignty to deal with the genetic resources in whatever manner in accordance to the established laws. Here the law is silence on the link that exist between the genetic resources and the TK, and the fact that, this TK need not always be in public domain, it may be individually owned.

To cement on the above it is argued that, the CBD convention has the qualifier that says ‘subject to national legislation.’ What if there is no existing national legislation, which recognizes indigenous people’s rights? Most countries, which have indigenous peoples, do not have such legislation<sup>91</sup>.



The arguments raised by Sem, seems to be valid since a number of African countries although they fight against bio-piracy at an international level by insisting the amendments of TRIPS Agreement have no rules/regulation in place in their domestic laws to curb this problem at all<sup>92</sup>.

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<sup>91</sup> See Sem T. Shikongo (2005) Report on the Threats to the Practice and Transmission of Traditional Knowledge Regional Report: Africa pg 16

<sup>92</sup> See the statement made by the Zimbabwe Legal and Parliamentary Affairs principal law officer Jameson Mupariwa, where he said that, Zimbabwe had no legal framework to protect traditional knowledge from piracy, and had identified this as a weakness in terms of protecting intellectual property. Mupariwa added that the absence of a law on IPR was prejudicing holders of traditional knowledge of the benefits they should be accruing from their knowledge. He made this statement in the African Regional Intellectual Property Organization (ARIPO) workshop on traditional knowledge in Africa, (Zimbabwe develops policy to protect Traditional Knowledge) available at, [http://english.peopledaily.com.cn/200612/15/eng20061215\\_332730.html#](http://english.peopledaily.com.cn/200612/15/eng20061215_332730.html#) visited on 8<sup>th</sup>/ February 2007, See also, Dr.Patricia Kameri-Mbote, Dr Philippe Cullet, Biological Diversity Management in Africa: Policy Perspective, available at <http://www.ielrc.org/content/w9902.pdf> Where they argue that, ‘Individual African countries are parties to a number of International Agreements concerning Management of Biological resources. There has also been a regional initiative. The challenge for these countries is to move

Moreover, wherever efforts to establish the same are being undertaken years may pass without the same being enacted or even being enforced if at all it will be enacted.

Another international instrument dealing with patent is the Patent law treaty<sup>93</sup>. The Treaty intends among other things to harmonies formalities that patent offices take in order to register patent. It may be argued that, this was a good ground for the developing countries to raise the issue of amendments of the TRIPS Agreement in their favor. However it is worth to note that, despite the fact that they raised such a point the reaction of the developed countries was a great obstruction to them.

The worse thing is that, developing countries proposal on the need to have provision for disclosure of origin of genetic materials, and proof of informed consent in accessing these genetic materials was dismissed. The developed countries argued that, the CBD provisions should not be construed as criteria for patentability and would be an administrative burden.

During the Patent Law Treaty negotiations, the industrialized countries rejected such proposals, arguing that they pertain to the substance of patent law, not procedure.<sup>94</sup> It can also be argued that, the Treaty is being discussed under WIPO, which is a UN agency, and not WTO as it is for TRIPS Agreement. So much so even if it had incorporated the proposal of the developing countries, yet it does not form part of the mandatory agreements of WTO, as a result enforcement of the same will not be effective as it is under WTO.

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from the realm of international and regional to the national sphere through effective and concrete legal institutional frameworks...'

<sup>93</sup> This Convention was put in place by WIPO in 2000, although not yet in force up to now

<sup>94</sup> See, ICTSD, A Debate outcome for Trade and Sustainable Development, Johannesburg 2002, available at, <http://www.ictsd.org>



### 3.1 PATENT REQUIREMENT UNDER TRIPS AGREEMENT

For an applicant to be granted patent in any office local or international one, the applicant must have to fulfill some requirements. These requirements are; first, the patentable subject matter must involve inventive steps, second it should be of industrial applications, and third, it should not be obvious in the sense that it's new or otherwise it should be novel<sup>95</sup>.

However the same provision provides for the exceptions on the other subject matters, which cannot be patentable under the same Agreement, where it states as follows;

“Members may exclude from patentability, plants and animals other than microorganisms, and essentially biological process for the production of plants or animals other than non –biological and microbiological process. However members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or any combination thereof.”<sup>96</sup>

From the above paragraph it is therefore clear that, patent shall be available for any inventions, whether products or process, in all fields of technology, provided that, they are new, involve an inventive step and are capable of industrial application. To cement on this, in *Diamonds' case*<sup>97</sup> the US Supreme court held that,

...process may be patentable, irrespective of the particular form of instrumentalities used can not be disputed... A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts performed upon the subjects matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as it is a piece of machinery. In the language of patent law it is an art. The machinery pointed out as

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<sup>95</sup> See the footnote No. 5 of Article 27 (1) of TRIPS Agreement for more elaboration of this

<sup>96</sup> See Article 27 (3) (b)

<sup>97</sup> See, *Diamond v Dierh* 450 US 175 (1981)

suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new results..”

The issue to be addressed at this juncture is that, when the TRIPS Agreement refers to newness, to who should it be new? This is because what might be obvious in one jurisdiction may be regarded as new in another jurisdiction. This kind of controversy may allow a product or process to be patented regardless the fact that it was known and applied in other countries for the same purposes as what purports to be new in another country.

In analyzing the question above it seem clearly that, the patent applicant should satisfy to the patent granting authority that his innovation is really new. However, the fact that, the current patent system does not recognize TK it is obvious that, once the applicant has proved that the innovation is new in the eyes of the granting authority then patent will be granted. To comment on the fact that the Patent granting authority are not aware of the existing TK when granting a patent, Manuel Ruiz <sup>98</sup> had the following to say,

“Had this traditional knowledge been known to patent authorities – examiners in particular at the time of review of patent applications, it may have been considered as prior art and, subsequently, may have defeated the claims that the invention was new and involved an inventive step. This would have assisted in the prevention of “bio-piracy”.

The author seems to suggest one point that, had the TK been considered as prior art, then the problem of Bio-piracy would have been finished. On one hand one can join hand his ideas, but on the other hand it is challengeable in the sense that, TK may be regarded as prior art but still it may guarantee piracy of genetic resources and associated TK from developing societies.

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<sup>98</sup> The International Debate on Traditional Knowledge as Prior Art in Patent System: Issues and Options for Developing countries (2002) Center for International Environmental Law pg 5-6

For example, US laws regard TK as prior art subject to conditionality. Such conditions are; that TK must have been registered in US, and that it should have been reduced in a form of writing by being publicized in journals in the country of origin.

These conditionality at first they indicate that US patent laws does not recognize foreign TK at all.<sup>99</sup> So much so, the conditionality at first negates the generality of the statement that, if TK would have been considered as Prior Art, it would have stopped bio-piracy.

Secondly, it shows a kind of discrimination between the foreign and the domestic TK in US. This is due to the fact that, if knowledge is new for the US it is novel even if it forms part of ancient tradition of other cultures in other countries. This controversy suggests that the problem of bio-piracy will be eradicated only where there are uniformity between the domestic and international regulations in protecting genetic resources and TK.

### **3.2 Meaning of Prior Art:**

The term Prior Art by it self refers to the complete body of knowledge, which is available to the public before a patent application is filed. TK is an example of prior art that always exists before the patent granted basing on TK has been issued by the patent authority.

The Fact that the knowledge had been in use by the African societies for quite long in treating various illnesses using the same tree or genetic resources, should be taken into account by the Patent granting authority. This will accord recognition to TK and reduce the rate of bio-piracy in African local societies.

However, this has been to the negative and instead the existing IPR regulations instead of fighting against bio-piracy it actually perpetrate the same. To justify this, there are no any international regulations that seem to reconcile the existing conflict between the law

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<sup>99</sup> See, Section, 102 of US Patent Act, which allows prior foreign knowledge, use and innovation to be excluded when the question of Prior Art is considered in relation to US Patent application, See also, US Patent System Legalize Theft and Bio-piracy available at, <http://www.organicconsumers.org/Patent/uspatsys.cfm> visited on October 17th 2006

and the practice in granting patent regardless of the fact that there is TK that existed before the application of the same.

The law should by no how allow any misappropriation of TK by adhering to the patent system that does not recognize the newness of the invention by the patent applicant, to comment on this Vandana Shiva has the following to say;

“If a patent system which is supposed to reward inventiveness and creativity systematically rewards piracy, if a patent system fail to honestly to apply criteria of novelty and non obviousness in the granting of patents related to indigenous knowledge then the system is flawed, and it needs to be changed. It can not be the basis of granting patents or establishing exclusive marketing rights...”<sup>100</sup>

The author goes on saying that, the problem of bio-piracy is a result of the western IPR system not the (domestic) Indian law. This means that, the Current IPR system need to change but not the domestic laws of India (developing countries).

With, this assertion, the researcher; would like to differ with the author in one way. That is, had Indian (domestic) laws and regulations on access and use of genetic resources and associated TK was intact and in favor of the local societies, the western Multinational Corporations would not have been able to access the said genetic resources. Thus it would have reduced if not stopped the acts of appropriation in India.

This shows the truth that, despite the fact that, the international IPRs regulations do not provide an answer to bio-piracy yet the domestic regulation will help in curbing this problem. Thus the African local societies will only benefit out of TK when they will manage to protect genetic resources and TK domestically and internationally as well.

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<sup>100</sup> See, US Patent System Legalizes Theft and Biopiracy, available at, <http://www.organicconsumers.org/Patent/uspatsys.cfm> visited on 17th October 2006

### **3.3 THE COMPLEXITIES OF EQUAL AND FAIR BENEFIT SHARING AS EXPERIENCED IN AFRICAN LOCAL SOCIETIES:**

The Convention on Biological Diversity is insisting on the access, equal and fair benefit sharing between the provider of the genetic resources and the users.<sup>101</sup> It further requires each signatory to make sure that the local societies benefit once others are utilizing their genetic resources and TK.

“Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of its biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”<sup>102</sup>

However, as it is seen above, its provisions on benefit sharing are not so detailed so as to provide answers to complex issues that may arise in the area of benefit sharing.

One may argue that, it contemplated one provider and one user of the genetic resources, or rather an organized group of providers and users. Moreover it even point that it will not deal with the agreements that were entered into between states prior it being in force.<sup>103</sup>

The insistence to have effective and detailed domestic laws and legal institutional frameworks to deal with the problem of bio-piracy as afore said should be highly considered now. This is because the western multinational corporations use the gap in

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<sup>101</sup> See Article 2 of the CBD Convention

<sup>102</sup> See Article 8 (j) of the Convention on Biological Diversity concluded at Rio de Janeiro in 1992

<sup>103</sup> It is also questionable as to whether it will deal with the misappropriation acts that took place before it comes into force. It is at this point where we see the need to have policy/ regulations that will also provide the basis for the challenge of the already pirated TK and the genetic resources in these local societies.

their favor if a country has no regulations at all or where are less detailed or even where they lack enforcement.<sup>104</sup>

Sometimes where there is lack of seriousness on the side of the enforcers or even the negotiators of the bio-prospecting agreement, these corporations are even ready to jeopardize the so-called equal and fair benefit sharing. A good example is drawn from Zimbabwe and the San people in the Southern part of Africa.

In Zimbabwe's case, the agreement between the Zimbabwe University (as a beneficiary) and Luasanne University was clear to the effect of showing how the parties will benefit out of the contract by filling a joint patent application.

However, the later proceeded applying for patent and eventually was granted at the detriment of the beneficiary. In reacting against this the Vice Chancellor of Zimbabwe University had the following to say;

“While the research agreement is by no means a perfect document, the University of Lausanne obviously made no effort to respect the content and spirit of the agreement. The conduct of Lausanne University clearly demonstrates that the illegal appropriation of biological resources from developing countries is still common practice by northern Universities (research institutions) and corporation”<sup>105</sup>

The case above is a representative of a number of anomalies that are likely to occur in African local societies, if there are no strict domestic regulations. These anomalies include the fact that, in this case only the Zimbabwe University was part of the benefit sharing agreement. The government and the other stakeholders like the local society were

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<sup>104</sup> This may happen because of lack of Institutional Legal Framework to enforce the said regulations

<sup>105</sup> See, The Government and University of Zimbabwe determined ton stop Bio-piracy by Swiss University. Available at, <http://www.evb.ch/ev/p25000453.html> visited on 17th December 2006

not involved. It is also argued that the medicinal plant was given to Lausanne University at a less than fair value.<sup>106</sup>

In recent case in Africa representing the unfair benefit sharing as mostly cited case is that of Hoodia. In this case the traditional Bushmen society received very low percentage of the royalty received by the research institution in South Africa. In analyzing this benefit sharing agreement between the San and the users of their TK, the legal adviser of the San Organization had the following to comment,

“Despite positive reactions by many stakeholders on this agreement, it has to be recognized that the provisions are highly restrictive with respect to the San as the original rights holders and highly protective with respect to CSIR as the current patent holder. For example, any intellectual property arising from traditional indigenous knowledge of use of Hoodia and related to CSIR belongs to CSIR, the San will not contest CSIR patent, the San will not enter into competing agreement with third parties, the San are not involved in the multi-million dollar licensing negotiations of Phytopharm, and they finally will not benefit from future product sales.”<sup>107</sup>

The two cases raised an issue in common when one refers to benefit sharing agreements. The issue is, to whom is this benefit actually intended to be shared? This issue is worth raised at this point because with the trend of two cases above it is clear that, the holders of the TK seem to be the neglected or rather oppressed by being the fourth in consideration of benefit.

The first are the western multinational corporation, the second are the research institutions (mostly Universities or research centers) and lastly we find local societies who are always being marginalized or exploited by these two big parties.

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<sup>106</sup> Ibid

<sup>107</sup> See, The Hoodia case: the San experiences with benefit-sharing agreements  
Side event at COP-8, 29 March 2006

In Hoodias' case for example, the South African research institute researched on the hoodia. It ultimately transferred its rights to a British pharmaceutical corporation. In this transaction, the research institute had a better share of benefit in comparison to the original holders of the knowledge about hoodia.<sup>108</sup>

However, when one considers the main concern of CBD convention, he also had to consider the state as the owner of all resources<sup>109</sup>. Thus, the issue of equal and fair benefit sharing is still been complicated at this juncture. It needs a clear explanation within the domestic regulations rather than at international level.

It is the strong standpoint of this thesis that, exploitation of the local communities in bio-prospecting agreements with the users of TK should be avoided. This can be achieved by setting a fixed minimum benefit sharing that the users should give to the local societies in any event their TK is used. Without this, the issue of equal and fair benefit sharing will still benefit the research institutions while leaving the holders of this valued knowledge with nothing.

The above idea is founded on the existing relations between the holders of TK and genetic resources in comparison with the users. The relation has always been between the two contracting parties, one (which is the user) always having the high bargaining power than the other (holders of TK).<sup>110</sup>

In his comments about the imbalance between the user and the holder of TK, (Mr. Murasoli Maran) the then Indian Minister of Commerce and Industry had the following to say,

“IPR laws must benefit all the holders of such IPRs equally - whether they are huge multinationals spending billions of dollars on research or traditional local

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<sup>108</sup> The same reason was also discussed in Zimbabwe's case where it was said that, the University was the only beneficiary hence it marginalized other stakeholders like the government and the traditional hillers.

<sup>109</sup> See the preamble of the CBD Convention that grants states sovereignty over their own biological resources

<sup>110</sup> See UK Governmental Commission on Intellectual Property Rights pg 85



communities where knowledge has simply been passed on from generation to generation”<sup>111</sup>

To achieve the said above balance in benefits, there need be effective laws and regulations on benefit sharing. These regulations need to be directed in protecting the interest of the local communities involved in bio-prospecting agreements.

The third example is of a plant<sup>112</sup> pirated from Tanzania where one can see clearly the complex issue of who are to be the beneficiaries on the same. It is seen to be a really long chain of stakeholders to the extent of fail to consider the issue of equity but rather fairness.

In Tanzanian case of bio-piracy as indicated<sup>113</sup> there is no any agreement on issues of equal and fair benefit sharing. Despite the fact that the company that holds patent on the plant (Syngenta) benefit out of it commercially in gardening and other associated uses<sup>114</sup>.

However, the way the plant finds its way to the hands of the Syngenta is a long chain. It is questionable whether the issue of equal and fair benefit sharing should involve the whole chain. The summary of it runs as follows,

“The patent discloses the source of the genetic materials that Syngenta used to be from the Royal Botanical Gardens in Edinburgh. The latter stated that they had received their seeds in 1982 from the Royal Botanical Gardens at Kew where they had been deposited “in 1976 by Christopher Grey-Wilson, a former president of the Alpine Garden Society.” Syngenta stated that it obtained the seeds it used in

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<sup>111</sup> See An International Seminar on Systems of Protection of Traditional Knowledge, New Delhi; by India and UNCTAD during 3-5 April, 2002.

<sup>112</sup> The plant has no direct link with medical use, (although there are arguments that it may be used for treatment of cancer, I found no where concrete evidence of the same) I find it a good example to be used in trying to explain how complex the issues of benefit sharing may be, which will have negative implication to the local societies who are custodians or even those who have conserved the environment in which the useful plant was found.

<sup>113</sup> See Antony Barnnet, *The new piracy: How West steals African Plants*, The Observer; August 27<sup>th</sup> 2006 available at, <http://www.gurdian.co.uk/science/story/html visited on 4th/ 12 2006>

<sup>114</sup> It is argued that, For those not from this part of the world, gardening has been one of the fastest growing hobbies in North America in recent years so the quest for the perfect trailing plant for hanging basket displays - while not exactly a cure for cancer - is potentially a great money-maker.

1990 and that when the company received the seeds, no one knew exactly which country they came from.<sup>115</sup>”

Who then should enter the agreement of benefit sharing between the users and the provider, should it be only between Syngenta and Tanzanian Government, or should it also involve the local societies of the place where the plant was found (Usambara Mountain)? What about other groups who were in one way associated with it, such as the Royal Botanical Gardens?<sup>116</sup>

Having in mind the above complexities existing in the general concept of equal and fair benefit sharing in using the genetic resources in developing countries, especially on the number and nature of the stakeholders involved. It is questionable, how far then the developing countries are prepared to face these complex issues.

These issues had to be addressed with the aim of protecting the interest of the traditional (local) community who are the custodians of the knowledge and the materials. These stakeholders use these materials and knowledge in furthering research and new discoveries. As shown above, these local societies are always forgotten. In an event they are remembered then, they are last group to be considered and always receive very little as their benefits despite the fact that, they are the originators of this knowledge.

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<sup>115</sup> See, Antony Barnett, The new piracy: How West steals African Plants, The Observer, August 27th 2006 available at, <http://www.gurdian.co.uk/science/story/html> visited on December 4th 2006

<sup>116</sup> See, ‘The comments on CBD, Intellectual Property and ABS’. ‘... the story illustrates some of the complexities of ABS. If Syngenta was to consider entering into a benefit-sharing agreement, who would it share the benefits with? The Royal Botanical Gardens in Edinburgh where it got the seeds? The Royal Botanical Gardens at Kew where the seeds had come from previously? The Tanzanian government - Tanzania being the country where the plant with the trailing characteristic was found? Or a local community in Tanzania? In all likelihood, a number of these players would probably need to be involved. ABS contract negotiations are rarely between one user and one provider. The multitude of different actors can make them costly undertakings - even before the benefit-sharing begins..., available at <http://karthryn.garforthmitchell.net>, visited on November 29<sup>th</sup> 2006.

### **3.4 THE DEVELOPED AND DEVELOPING COUNTRIES BALANCE OF INTEREST ON ACCESS AND USE OF GENETIC RESOURCES AND ASSOCIATED TK.**

Having seen the pot-holes in the international instruments dealing with the protection of TK in African local societies, it is questionable as what should be done for there to be a balance between the holders of TK and the users?

In addressing the above issue, it can be said that, the provision of Article 27 of TRIPS Agreement had a safety valve to these African societies although its implementation seems to be a problem.

The provision states that it will be reviewed in first five years after the agreement come into force. The agreement came into force in 1995, thus it ought to have been reviewed in the year 2000 so as to address other issues among which TK is the main.

The African countries and other developing countries that are being marginalized by the current IPR regime as it is biased towards the western approach have shown their interest to have the TRIPS agreement amended by presenting their proposals in various meeting discussing the same.

However, the developed countries oppose the African or rather the developing countries approach, by providing their own approach in which they think will be wise to amend TRIPS agreement to handle the current trend in curbing bio-piracy. This situation forms two opposing side on the modality of amendments.

The TRIPS amendments were mainly focused on how to deal with the commercial use of TK and genetic material by those other than the communities or countries where they originate. It was mainly directed where TK are the subject of patent applications, it was also aimed to ensure that the TRIPS Agreement and the UN Convention on Biological Diversity (CBD) support each other.

It should be noted here that the Doha round of negotiation had also mandate to discuss issues pertaining TK but unfortunately it bears no fruits as it collapsed<sup>117</sup>.

It is at this juncture one need to see the possibilities of balancing the interests of these two groups. This situation roughly can be said to represent the users (the western countries) and the providers that represent the developing countries.

The developed countries would like TK to be commercialized while maintaining the current position of the TRIPS Agreement that actually does not recognize TK. On the other hand the developing countries would like the protection of TK, both against commercialization<sup>118</sup> and in commercialization, and at the same time pioneering for the amendments of the TRIPS Agreement to the extent of recognizing TK.

The developing countries' proposal<sup>119</sup> is to the effect that, the TRIPS Agreement needs to be amended to contain the requirement for the disclosure of the origin of genetic materials that are used in any discovery of any drug (subject matter of patent). It also requires the patent applicant to provide evidence of the contact of benefit sharing in between the applicant and the local society in developing country who are the custodians of the TK.

All this is aimed at assuring protection of TK and realization of fair and equal benefit sharing arising from the use of the biodiversity and TK.<sup>120</sup> However this proposal seem

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<sup>117</sup>See, Paragraph 19 of the 2001 Doha Declaration, which says that, the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity and at the protection of traditional knowledge and folklore

<sup>118</sup> In the sense that, commercialization of TK should not interfere with the religious or moral belief of some societies in Africa.

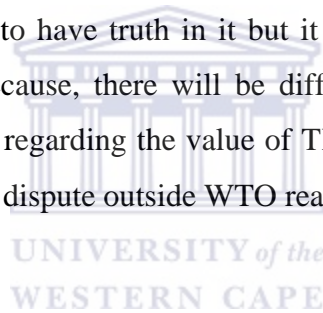
<sup>119</sup> The proposal put forward by group represented by Brazil and India and including Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, available at [www.wto.org](http://www.wto.org)

<sup>120</sup> See, the TRIPS: Reviews, article 27.3(B) and related issues background and the current situation, available at, [www.wto.org](http://www.wto.org) visited on 6<sup>th</sup>/February 2007

also to be general in the sense that it does not require the fixed percentage (minimum benefit) below which the users will not be allowed to give to the local societies in developing countries. It is the considered view of the researcher that the same need to be provided for in the domestic regulations so as to assure protection of the local societies against the western corporations and other stakeholders, who are involved in the bio-prospecting agreements.

The developed countries however, are in opposition to the developing countries' proposal as they argue that, they would like the issue of benefit sharing be considered bilaterally between the user and the provider of the biological resources<sup>121</sup>. They justify this by arguing that, even if the developing countries' proposal would have been accepted yet, there should be a bilateral agreement between the provider and the user.

However this argument seems to have truth in it but it does not nullify the developing countries' proposal. This is because, there will be different approach in the countries hence distorting the uniformity regarding the value of TK, also the issue of enforcement will be a problem as it will be a dispute outside WTO realm hence affecting the end result of the initiatives taken.



### **3.5 Conclusion:**

In summary it can be said that, there is a need to have TK being protected against bio-piracy done by the western pharmaceutical corporations. It is through protection in both domestic and international regulation (having TRIPS agreement amended) where the local society will benefit out of their knowledge.

To be more precise, the domestic regulation should provide for a minimum profit sharing percentage between the user and the local society. Moreover, effective legal institutional framework dealing with issues of access to genetic materials need to be established. This

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<sup>121</sup> See, US is of the view that, the Convention on Biological Diversity's objectives on access to genetic resources, and on benefit sharing, could best be achieved through national legislation and contractual arrangements based on the legislation, which could include commitments on disclosing of any commercial application of genetic resources or traditional knowledge. Available at [www.wto.org](http://www.wto.org)

will help to avoid exploitation of the local society by the other financially giant stakeholders who forms part of the benefit sharing in bio-prospecting agreements. In doing this the IPR regulations will definitely be striking the balance of interest between the users and the providers of TK.



## CHAPTER FOUR

### THE DOMESTIC REGULATIONS ON PROTECTION OF TK IN SELECTED AFRICAN COUNTRIES

#### 4.1 SOUTH AFRICAN REGULATIONS WHICH GOVERNS TK.

##### 4.1.1 Introduction

South Africa has a number of well-established regulations, which governs the access, use, and patenting of the genetic resources which are always associated with TK. These regulations are aimed at assuring sustainable, equal and fair use of the genetic resources and associated TK to the nation and any other stakeholders like the local societies. These regulations are enacted as a result of recognizing the need to protect the bio-diversity. Bio-diversity has to be protected, as many populations are directly dependant on it for job, food, and shelter, medicines and spiritual well being<sup>122</sup>.

##### 4.1.2 Protection through Biodiversity Act

The protection of biodiversity in South Africa by a special enactment of the law that regulates the access, use and benefit sharing in the country, has in one way protected the rights of the local societies. The provisions of the law and the institutions established by the law has a lot of contributions in assuring sustainable, equal, and fair use of the genetic resources between the stakeholders.

To begin with the Biodiversity Act<sup>123</sup> the Act was initiated by the South African Ministry of Environmental affairs and Tourism. The Act establishes some regulations on access and use of genetic resources in South African jurisdiction...

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<sup>122</sup> See The South Africa's National Bio-diversity Strategy and Action Plan 2005.

<sup>123</sup> Republic of South Africa, Biodiversity Act No. 2006

“No person may, without a permit issued in terms of Chapter 7-  
(a) engage in bio prospecting involving any indigenous biological resources; or  
(b) export from the Republic any indigenous biological resources for the purpose of bio prospecting or any other kind of research.<sup>124</sup>”

This means that no person shall without previous approval of the National Biodiversity Authority obtain any biological resource occurring in South Africa or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

The Act seems to protect the interest of the holders of TK and the general concern of the genetic resources. The general requirement on access and use of genetic resources seems to have been included in this Act. Requirements of prior informed consent of the holders of the genetic resources and TK and proof of benefit sharing agreement between the stakeholders and the local society. This by itself shows a good approach by the law in protecting the rights of the locals.

“If a stakeholder has an interest as set out in subsection (l) (a), an issuing authority, may issue a permit only if,

- a) the applicant has disclosed all material information relating to the relevant bio prospecting to the stakeholder and on the basis of that disclosure has obtained the prior consent of the stakeholder for the provision of or access to such resources;
- b) the applicant and the stakeholder have entered into-
  - (i) a material transfer agreement that regulates the provision of or access to
  - (ii) a benefit-sharing agreement that provides for sharing by the stakeholder such resources; and in any future benefits that may be derived from the relevant bio prospecting; and

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<sup>124</sup> See Section 81 (1) of the South African Biodiversity Act 2006



- c) the Minister has in terms of sections 83(2) and 84(2) approved such benefit-sharing and material transfer agreements.”

From the above provision provides a clue that the minister concerned has to approve the benefit sharing agreement in any bio prospecting agreements between the local societies and other stakeholders<sup>125</sup>. This might be a good approach if at all the minister may be serious in defending the rights of the local societies.

Thus in any event where in the benefit sharing agreement the local societies seems to be marginalized the minister may withhold his right to approve the agreement hence no permit will be granted. Otherwise, the local societies are still subjected to the giant stakeholders who will always marginalize them unless there are clear set rules or regulations on minimum benefit sharing to these societies.

#### **4.1.3 Established Institutions**

The Act has established an institution to enforce the Act, this shows the seriousness of the initiatives in protecting the biodiversity and TK associated with. The Bio prospecting Trust Fund was established to take care of the benefit sharing agreements between the stakeholders in these agreements.

“A Bio prospecting ‘Trust Fund is established into which all moneys arising from benefit-sharing agreements and material transfer agreements, and due to stakeholders, must be paid, and from which all payments to, or for the benefit of, stakeholders must be made.”<sup>126</sup>

The institution like this will be helping the local societies in negotiation of the benefit sharing agreement where the government will also be a party. However, the Minister may exempt the indigenous biological resources from the above provision. In an event the

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<sup>125</sup> See also section 84 (2) of the South African Biodiversity Act 2006

<sup>126</sup> See Section 85 (1) of the South African Biodiversity Act 2006

minister exercise this, the local societies will be left vulnerable in hands of the giant stakeholders in bio prospecting agreements.

Generally, the situation above shows that the rate of bio-piracy in South Africa will be cut down if not stopped by this law and the established institutions to regulate the access and use of genetic resources.

#### **4.1.4 Protection through Patent**

Regarding patent requirement, the law has changed to reflect the need to protect TK and thus assuring equal and fair benefit sharing between the stakeholders of genetic resources and the associated TK. For example, the current amendment of Patent Regulations in South Africa shows that TK and genetic resources are being protected. The provisions in the regulation states as follows;

“Where the Form P26 contains a statement that the invention for which protection is claimed is based on or derived from an indigenous biological resource, a genetic resource, or traditional knowledge or use, the applicant shall, before acceptance of the application furnish the registrar with proof of his or her title or authority to make use of the indigenous biological resource, the genetic resource, or the traditional knowledge or use, by lodging with the registrar one or more of the following:

- (a) a copy of the permit issued in terms of Chapter 7 of the National Environmental Management: Biodiversity Act, 2004;
- (b) if applicable, proof that prior consent had been obtained as contemplated in section 82(2) (a) or 82(3) (a) of the National Environmental Management: Biodiversity Act, 2004;
- (c) if applicable, proof of a material transfer agreement as contemplated in section 82(2) (b) (i) of the National Environmental Management: Biodiversity Act, 2004;

- (d) if applicable, proof of a benefit-sharing agreement as contemplated in section 82(2) (b) of the National Environmental Management: Biodiversity Act, 2004;
- (e) if applicable, proof of co-ownership of the invention for which protection is claimed;
- (f) any other proof to the satisfaction of the registrar.<sup>127</sup>,

From the above provision, it will be noticed that the first requirement is indispensable. However, requirements numbered (b-f) seems to be in alternative. This means that it will depend on the nature of the agreement reached between the holders of TK and the other stakeholders. If two or more elements as stated in (a-f) are available, then those documents will be necessary in patent application.

In this amendment it is clearly seen that it supports the Biodiversity Act that regulates on access and use of the genetic resources and associated TK. The domestic regulations in South Africa seem to be interlinked in a good way to assure the protection of environment, genetic resources and associated TK.

## 4.2 TANZANIAN REGULATIONS ON TK

### 4.2.1 Introduction

Tanzania is a member country of African Intellectual Property Rights Organizations (ARIPO). In this organization there are some agreements on issues of Intellectual Property like patent. A good example of the agreement in this organization is, Harare Protocol<sup>128</sup>. This shows that Tanzania apart from being bound in its own local

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<sup>127</sup> See South African Patents-memorandum on prosecuting a pct national phase application in South Africa (revised May 2006 - patent regulations amended)

<http://www.hahn.co.za/patent-information.htm>; accessed on 17<sup>th</sup>, December 2007

<sup>128</sup> The Protocol on patents and industrial designs within the framework of the African regional intellectual property organization (ARIPO), (adopted on December 10, 1982, at Harare (Zimbabwe), and amended by the Administrative

regulations, it is also bound at International level in accordance with the agreements it has entered into with other countries<sup>129</sup>. Domestically, there are regulations like the Patent Act, Forest Act<sup>130</sup>, the National environment Policy and The Traditional and Alternative Medicines Act<sup>131</sup> that may also have impact on genetic resources and associated TK.

## **4.2.2 Critical Analysis of the Regulations that Governs TK in Tanzania**

### **4.2.2.1 Institutional Arrangements**

Generally speaking, the Tanzanian bio-diversity protection is not regulated under one ministry and a well-established legal institutional framework as compared to South Africa<sup>132</sup>. In the exploration and export of floral resources of potential medicinal value, currently is regulated by various ministries and departments such as:

- The Department of Agriculture with cooperative societies,
- The Departments of Natural resources and Tourism, and
- The Departments of Trade and Industries, and Health.

Because of the various stakeholders involved in the conservation and utilization of biodiversity, the law does not say anything about specific plant species. For example, under the Ministry of Agriculture and Cooperative Societies, the Natural Agricultural Products Law of 1969 deals with the control of sales, transport, storage, processing and trading of agricultural resources; while the Ministry of Tourism and Natural Resources deals with the conservation and management of forests and forest products focusing on

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Council of ARIPO on December 11, 1987, April 27, 1994, November 28, 1997, May 26, 1998, November 26, 1999, November 30, 2001 and November 21, 2003 and as amended by the Council of Ministers on August 13, 2004)

<sup>129</sup> See, Annexure B, that contain the list of member states of Harare Protocol and date on which state become a party to the protocol.

<sup>130</sup> Act No 7 of 2004

<sup>131</sup> Act No. 23 of 2002

<sup>132</sup> This has been seen in the previous part of this chapter dealing with South African regulations on TK.

forest reserves. There is no emphasis on establishing a unified policy among different ministries (e.g. the Ministry of Trade and Industries and the Ministry of Health), to guide the collection and export of medicinal resources.

Regulations governing the exploration, export, and conservation of fauna and marine resources are issued by the relevant departments of different ministries. Various regulations from different ministries exist but there is no single regulation that spells out how to control and regulate the exploration, export, and conservation of medicinal resources derived from animal and marine life.<sup>133</sup>

There are other institutions that deal with the regulations of TK and biodiversity in Tanzania. These institutions include the local authorities that deals with the issuing of permit to any one with a license to conduct research in local reserved forests. Also there is the National Research Council which regulates all research based activities in all disciplines.<sup>134</sup> However, these institutions have their weakness in formulating and implementation of the regulations as are discussed here under.

#### **4.2.2.2 National Environmental Policy**

The National environmental policy has one among other objectives, to ensure sustainable and equitable use of resources in meeting basic needs in the society. (No connection with the quotation below)

‘To ensure sustainability, security and equitable use of resources for meeting the basic needs of the present and future generations without degrading the environment or risking health or safety’<sup>135</sup>

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<sup>133</sup> See, Sophia Twarog and Promila Kapoor, (Ed), protecting and promoting systems, national experiences and international dimensions, (2004) United Nations, New York and Geneva, pg 18

<sup>134</sup> See Regulation 22 (6) of the Draft of the Traditional and Alternative Medicines (Regulation of Materia Medica) Regulations 2007

<sup>135</sup> See, United Republic of Tanzanian, National Environmental Policy, December 1997, pg 4

However, the policy is silent on the issue of access and use of the genetic resources and associated TK available in Tanzania for the benefit of Tanzanians. One could imagine that the reference to sustainable use of resources in the policy would encompass all these. And in this era of wide spread of bio-piracy the policy ought to have been clear and detailed on the issues of access, use and benefit sharing. This would have assured the society at grass root of the benefit out of their biodiversity and TK. Unfortunately, there is no such a thing.

Additionally, the policy does not address on the need to have established legal institutions controlling the rights of the societies that depend on environment for their healthy, and in addressing the likely effects of commercialization of the bio-resources.

The policy is categorically explaining about the conservation of the forests that contain biological diversity and genetic resources. However, it is silent as to whether these resources can be commercialized or not. Furthermore, if they are commercialized the policy is not clear on what criteria should the responsible officer deal with for the benefit of Tanzania. For examples, issues of negotiating about semi-processing industry in Tanzania, or value added genetic resources before they are to be sold abroad, or even issues of benefit sharing through royalties.<sup>136</sup>

#### **4.2.2.3the Draft Traditional and Alternative Medicine Regulations 2007**

Regarding medical research on traditional herbs in institutions in Tanzania, it was revealed that the researchers always depend on the information from the local societies in their medical discoveries.<sup>137</sup> This being the case, the institutes always has a close ties

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<sup>136</sup> See Tanzanian National environmental Policy, 1997, pg 18, although the issue of royalties is well covered under the Tanzanian Forest Act, while other issues left aside.

<sup>137</sup> See annexure C for the Questionnaires issued in this research.

with the local societies in training them and raising their awareness about the need to disclose their knowledge in traditional medicines.

However, there is a loophole seen in dealing with the genetic resources and the associated TK in these research institutions. This loophole is based on the fact that there are no special regulations/policy/guidelines in place to regulate the amount of genetic resources to other research institutions abroad.<sup>138</sup>

This by it self provides a lacuna for appropriation to take place in our jurisdictions. This lacuna is not only under these institutions but generally reflect the weakness in the National Research Council, which is the head of such institutions. That is to say, the national research council ought to have laid down the rules/guidelines to regulate the amount of genetic resources to be exported for further research abroad.

Currently, there are on going initiatives in assuring that the research institutions are provided with the regulations or policies to protect the transfer of genetic resources TKB.<sup>139</sup> In their first draft regulations<sup>140</sup>, the following loopholes can be pin pointed:

Firstly, the protection of the local societies seems not to be the concern of the regulation. This is reflected in the draft regulations where there is no any provision with a fixed percentage of what will amount to benefit sharing to the local societies when entering into bio-prospecting agreement with the economic giant institutions or western corporations.

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<sup>138</sup> This was revealed in the reply of the questionnaires issued on 16th March 2007 to Dr E. J

Kayombo (Head of Department of Medical Botany, Plant breeding and Agronomy. Institute of Traditional Medicine, Muhimbili University Collage; University of Dar es Salaam)

<sup>139</sup> These initiatives are made under Section 55 (1) and (2) of the Traditional and Alternative Medicines Act No. 23 of 2002

<sup>140</sup> See the annexure C

However, part VI of the draft regulations, which deals with the research, has made some reference on the memorandum of understanding in collaborations with the local practitioners. The National Research Council has to be satisfied with the memorandum entered into for the interest of the local practitioners and the country.

“The Council shall satisfy itself that the memorandum of understanding safeguards the interests of traditional and Alternative Health Practitioners, the council and the country.<sup>141</sup>”

The above-proposed draft could be said to constitute to the protection of the interest of the local societies in any bio-prospecting agreement, although not so straight to the point of establishing a fixed percentage as pinpointed in the previous paragraph.

Secondly, the regulations, did not pin point the criteria used in granting a permit for the export of the material medical or in any bio-prospecting agreement. This by itself seems to be left to the discretion of the permit granting authority. The draft regulations ought to have to spell out the criteria's like;

- a) Mandatory value added processing industries being established in our country
- b) Establishing subsidiary industries in the areas of origin of the traditional herb that lead to medical discoveries.
- c) Establishing large estates in cultivation of the herb that was discovered to have medicinal value
- d) Encouraging joint-ventures in the pharmaceutical and research experts between the local and foreign institutions or corporations.
- e) Establishing research institutions in our jurisdiction and entering into an understudy with our local experts.
- f) Filling for joint patent application in an event their research has positive results in any drug discoveries.

If the criteria above will be taken into consideration in all the bio-prospecting agreements, the society will get more benefit rather than royalties by themselves.

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<sup>141</sup> See, Regulation 22 (6) of the Draft of the Traditional and Alternative Medicines (Regulation of Materia Medica) Regulations 2007



#### 4.2.2.4 Protection through Forest Act

Despite the above stated loopholes, part VII of the Forest Act<sup>142</sup> prohibit any export of any forest produce<sup>143</sup> without a permit from the authority. This part of the Act deals with trade in forest produce. It is thus seen in one way that the forestry product are protected from plunder by the western corporations if at all the law is to be effectively enforced.

“No person shall export or enter for export any timber or other forest produce  
Unless;

- (a) he has a valid export certificate issued by the Director in respect of that timber or other forest produce; or
- (b) that timber or other forest produce has by an order made by the Minister and published in the *Gazette* been exempted from the provisions of paragraph (a).<sup>144</sup>,”

The problem is still with the produce, which are not forestry. This is because the Act is silent on the issue of non-forest produce. It means that, where a traditional healer has managed to have his own herbal garden, he is not under the umbrella of the Act. This exposes his knowledge about the medicinal value in those herbs and hence vulnerable to bio-piracy. This is taking into account the techniques used by the western pharmaceutical

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<sup>142</sup>Tanzania Forest Act, Act No 7 of 2004

<sup>143</sup>See definition section of the act , where the term forest produce is referred here to mean, “anything which is produced by or from trees or grows in a forest or is naturally found in a forest and includes bamboos, bark, bast, branch wood, canes, charcoal, earth, fibers, firewood, fruits, galls, gums, honey, latex, laths, leaves, litter, natural varnish, peat, plants. Poles, reads, resin, roots, rushes, sap, sawdust, seeds, slabs, timber, trees, thatch, wattles, wax, wild silk, withies, wood shes, wood oil, and any other living or inanimate object declared by notice in the *Gazette* to be forest produce for purposes of this Act;”

<sup>144</sup> See Section 58 of the Tanzania Forest Act, Act No 7 of 2004

corporations in pirating the TK, and the nature of the stakeholders where we have the giant institutions and the local society, which has low bargaining power.<sup>145</sup>

The Act and its regulations also has some weakness in the sense that it does not set the minimum benefit sharing to the local societies or individuals who might have any contribution in any medicinal discoveries in the forest. This is in relation to the fact that the local societies or individuals are always being marginalized and oppressed by the other stakeholders in the bio-prospecting agreements due to their low bargaining power.

#### **4.2.2.5 Protection through Patent Registration**

As pointed before Tanzania is a member of ARIPO, through this organization all member states are governed through same requirements in patent registration. Therefore in any application for patent registrations in Tanzania the following requirements have to be fulfilled. Such requirements are;

“A patent application shall:

- i) identify the applicant;
- ii) contain, as prescribed, a description of the invention, a claim or claims, a drawing or drawings, where necessary and an abstract;
- iii) designate the Contracting States for which the patent is requested to be granted;
- iv) be subject to the payment of the prescribed fees.<sup>146,</sup>”

As the requirements seen from above there is no emphasis on the disclosure of genetic materials that are used in the subject matter of the patent. Also, the protocol is silent on

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<sup>145</sup> As seen from the previous chapters, (chapter 2 pg 26) western pharmaceutical corporations come under the cover of tourism, they may also stay with the local society studying their ways of life, ultimately they take the knowledge for their own use

<sup>146</sup> See, Article 3 (1) of the Harare Protocol

the issue of proof of benefit sharing agreement between the users and holders of TK in its member states or any other stakeholders.

It can also be observed that, the local societies are not protected against the giant stakeholders by any provision that would have set a minimum benefit sharing in any event of such agreement. These requirements would reflect the true picture of the protection of TK and equal and fair benefit sharing between the stakeholders and the local societies in Tanzania.

### **4.3 CONCLUSION**

Having in mind the complexities as discussed in chapter three, it is obvious that the local societies in Tanzania and other member states of ARIPO, needs to be protected once their TK is being used. Comparatively, the South African regulations dealing with access, use and benefit sharing on the genetic resources and TK are supporting each other hence assuring full protection if at all the enforcement will not be ignored. Tanzania has a lot to learn from the South African development in the law and the institutions dealing with the genetic resources and TK as seen above.

## CHAPTER FIVE

### 5.0 OBSERVATIONS, RECOMMENDATIONS AND CONCLUSION

#### 5.1 Observations

This work witnessed existence of loopholes in both international and domestic IPR regulations governing the protection of TKB. As has already been seen, the international regulations are still biased towards the western knowledge while according no recognition to TK at the multilateral organization. In domestic regulations, loopholes are found in the research institutions, which have neither regulations nor guidelines on the amount to be transferred to other research institutions abroad.

Also, this work witnessed the local societies receiving little or no attention concerning what is going to be their benefit in any bio-prospecting agreements with the economically giant western corporations.

Further observations regard to the criteria used (guidelines) in entering into the bio-prospecting agreement. This research witnessed the absence of set guidelines of criteria to be referred when entering into such agreements with other stakeholders. It is left to the discretion of the negotiating officers to decide what should be given to the state and the local society involved in the deal.

The other observation is the incomparability existing between the regulations dealing with the protection of genetic resources and TKB and the regulations dealing with patentability. This work found that to some extent the regulations in protection of genetic resources and associated TKB are tight while those dealing with patentability are loose. This is proved due to the fact that the protection granted in the Forest Act, the Traditional and Alternative Medicines Act, and the National environment Policy is not reflected in the Patent Act.

From the above observation it is obvious that if a person will be able to pirate the genetic resources and associated TKB in our country and advance the same into a drug, he can apply for patent protection in our country as well. This will in turn result to the injustices that this work intended to address and avoid them in local societies in Africa.<sup>147</sup>

Moreover, this work observed that there is no single established institution to regulate the access and use of biodiversity and associated TK in Tanzania. There are a number of authorities regulating issues of biodiversity; these include the National Research Council, which deals with the registration and licensing<sup>148</sup>, and the Director of Forests, who deals with the research permit in the forests.<sup>149</sup>

The director of forest also has power to appoint licensing and registration officers,<sup>150</sup> at the same time the Act, allows research in medicinal plants as among other activities to be carried in the forests.<sup>151</sup> This shows the likelihood of having the registration, licensing and permit being issued by the office of the director of forests, hence disregarding the provision of the draft regulations. There need be a reconciliation of these two regulations to avoid unnecessary clashes in the law and thus making it easy to implement.

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<sup>147</sup> For detailed discussion of the injustices that could occur due to the weakness of these regulations, see chapter two, pg 21.

<sup>148</sup> See, regulation 22(1) &(2) of the proposed Draft of the Traditional and Alternative Medicines (Regulation of Materia Medica) Regulations 2007

<sup>149</sup> See section 49 of the Forest Act 2004

<sup>150</sup> See section 6(3) of the Forest Act 2004

<sup>151</sup> See section 49 (c ) of the Forest Act 2004

## **5.2 RECOMMENDATIONS**

### **5.2.1 Recommendations on the International regulations.**

That the international regulations need to be amended to reflect the balance of interest between the western and the African local knowledge so as allow TK be recognized at the multilateral level. This can be achieved having the TRIPS Agreement amended to contain requirements like; proof of benefit sharing agreement not below a certain fixed percentage as the council for ministers will deem fit, proof of prior informed consent of the holders of genetic resources and TK, in any inventions which involve TK.

That these amendments need to be done within the multilateral sphere and not under the UN initiatives as it will jeopardize the position of the developing countries in Trade negotiations. It should form part and parcel of the mandatory agreements of the WTO rules so as to assure easy enforcement of these rules.

### **5.2.2 Recommendations on the domestic regulations**

That, there should be regulations or guidelines to limit the extent of the genetic extract to be transferred to other research institutions abroad. The regulation may limit this by inserting a condition that if the abroad researcher will need amount of genetic extract beyond a certain fixed quantity, then the researchers has to establish their research centre in our country and enter into joint venture or understudy with our local researchers.

That there should be special regulations to safeguard the interest of the local societies or individuals in bio-prospecting agreements to assure their benefits are not fraudulently taken by the users of TKB. Establishing minimum standards of what should be their financial benefit in these agreements can achieve this. This minimum standard can be in terms of fixed percentage of the general benefit to be accrued out of the output of the research basing on the TK given by the local society or individual

That there should be guidelines that shall direct the negotiating officers in all the bio-prospecting agreement on how to negotiate for the benefits of the local societies and other stake holders involved in such agreements. This will avoid the likely hood of having the local society's rights being jeopardized by the giant research institutions who are mostly the users of TK.

These guidelines must exist in these institutions dealing with biodiversity rather than operating by the discretion of the negotiators. Their discretions should be guided by the existing guidelines set by the National Research Council, for the interests of the nation, and other stakeholders associated like the local societies/individual and the research institutions.

That, there should be compatibility between the regulations governing access and use of biodiversity and the regulations dealing with patentability of innovations arising out of use of biodiversity. The Harare Protocol and Tanzania Patent Act need to be amended to include requirements such as those reflected in the South African Patent Act<sup>152</sup>

Recognition local provisional patent to TK to local African societies, which can not invest or research to come up with a well proved scientific formula on a number of traditional medicines. It can simply be granted by a mere description by the traditional healers to the appointed officials, of the type of the herb and how is it used in offering treatments. This will also provide a basis of development in research by Universities in the developing world as well as developed world.

Also, petty patents will allow for protections similar to those of patents, but for knowledge consisting of a less-detailed inventive step. Thus, the local societies must insist on the need to enact laws which provide for such provisions so as to be protected by their local legislations.

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<sup>152</sup> For more details see chapter four, pg 4.

### **5.3 CONCLUSION**

Conclusively, it can be argued that the local societies need to be protected through both, the local and the international IPR regulations. As seen from the above findings, the protection offered to the local societies is not sufficient to provide the society with the full enjoyment (benefits) of their TK.

The International Regulations are still biased towards Western knowledge and thus ignore the recognition of the local knowledge. This will still have negative implications in African local societies and their TK. However, as shown above if the local regulations in the African local societies will be strict in protecting TK, it will assure benefit sharing in between the user and the provider of TK.

It is the humble submission of the researcher that the local regulations need to be strictly aimed at protecting genetic resources and associated TK. This will help, firstly, to reduce the rate of bio-piracy in African local societies and secondly, to assure sustainable use of the genetic resources and associated TK, thirdly, to assure equal and fair benefit sharing arising from the use of the local societies' knowledge in the current medical scientific discoveries.



## ANNEXURE A.

### AFRICAN COUNTRY'S SIGNATORIES TO THE UNITED NATIONS CONVENTION ON BIOLOGICAL DIVERSITY.

A total of 39 countries in Africa are signatories to the CBD Convention as here under listed: (<http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt> last accessed on 13<sup>th</sup> February 2007)

- 1) Algeria,
- 2) Benin,
- 3) Botswana,
- 4) Burkina Faso,
- 5) Cameroon,
- 6) Cape Verde,
- 7) Chad,
- 8) Congo,
- 9) Democratic Republic of the Congo,
- 10) Djibouti,
- 11) Egypt,
- 12) Eritrea,
- 13) Ethiopia,
- 14) Gambia,
- 15) Ghana,
- 16) Kenya,
- 17) Lesotho,
- 18) Liberia,
- 19) Libyan Arab Jamahiriya,
- 20) Madagascar,
- 21) Mali,
- 22) Mauritania,
- 23) Mauritius,
- 24) Mozambique,
- 25) Namibia,
- 26) Niger,
- 27) Nigeria,
- 28) Rwanda,
- 29) Senegal,
- 30) Seychelles,
- 31) South Africa,
- 32) Sudan,
- 33) Swaziland,
- 34) Togo,
- 35) Tunisia,
- 36) Uganda,
- 37) United Republic of Tanzania,
- 38) Zambia,



**39) Zimbabwe**  
 Member states of Harare Protocol

States party to the Protocol	Date on which State became
Botswana .....	May 6, 1985
The Gambia .....	January 16, 1986
Ghana .....	April 25, 1984
Kenya .....	October 24, 1984
Lesotho .....	October 23, 1987
Malawi .....	April 25, 1984
Mozambique .....	May 8, 2000
Namibia .....	April 23, 2004
Sierra Leone .....	February 25, 1999
Sudan .....	April 25, 1984
Swaziland .....	March 17, 1988
Uganda .....	April 25, 1984
United Republic of Tanzania .....	September 1, 1999
Zambia .....	February 26, 1986
Zimbabwe .....	April 25, 1984



## ANNEXURE C

### REQUEST FOR ACCADEMIC ASSISTANCE

Dear Madam/Sir

I am a student of UWC in the faculty of law. Currently I am doing my research in International Economic Law.

I am kindly requesting your office to assist me in my research by filling in the questionnaires attached with this letter.

Also, with this letter I enclose an identification letter from my faculty, for brief information about my research see below.

ATTACHED HERE WITH ARE THE QUESTIONNAIRES OF MY RESEARCH.

**BENEFIT SHARING FROM TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPEERTY RIGHTS IN AFRICA: AN ANALYSIS OF INTERNATIONAL REGULATIONS**

This research is being done due to the wide spread of Bio-piracy in African local societies by the developed countries. It is the same developed countries that resist against inclusion of disclosure of origin of the genetic resources in the TRIPS Agreement.

This makes the international intellectual property regulations biased towards the western scientific knowledge while according no recognition to Traditional Knowledge (TK). This has effects in increase of spread of bio-piracy and denial of local society of any proceeds out of their TK.

The main aim of this research is to provide recommendations in African local society on the need to have domestic regulations (to protect their TK) on access and use of the genetic resources and associated TK. This will help these societies in regulating their TK and thus derive benefit out of it whenever used. Ultimately, if the recommendations be adopted will combat the problem of wide spread of bio-piracy.

Your answers which, I will be glad to receive at the end of the next week; (16<sup>th</sup> March 2007) will be kept confidential. Also, I will use them only for the purpose stated above.

Your contribution will also be acknowledged at the end of my research, prove of which will be evidenced upon receipt of the electronic copy of my final paper.

I pass my thanks in advance for your cooperation.

Yours Faithful

Ombella John S.

LL.M International Trade and Investment Law in Africa

University of the Western Cape

E-mail address: [ombella@gmail.com](mailto:ombella@gmail.com)/[ombella@yahoo.co.uk](mailto:ombella@yahoo.co.uk)

Mobile No. +255713227298



#### QUESTIONNAIRES:

What are the criteria used by the researchers in identifying the plant with medicinal value in their research?

- ❖ Do they consult the traditional society for information?.....
- ❖ Do they just troubleshoot in ascertaining the plant!.....

1. How is the local community involved in the benefit of the research in your Institutions?

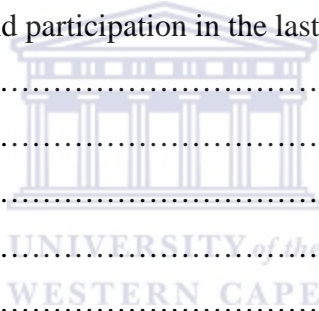
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.....  
.....

2. Does your institution distinguish between the herbal medicines that its knowledge is already in public domain and the one, which is still held by an individual?.....

.....

3. What is the approach and participation in the last circumstance!

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4. Is there a set regulation or policy regulating the amount of genetic materials to be transferred/ exported for research abroad in other Universities!

.....  
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.....

❖ What about for commercial purposes! What are the differences between the two?

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❖ Are there any plan going on or in future to develop capacity to prepare medical plants extracts for sale on the World Market? Or is there any link between this trade and conservation and community development?

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The logo of the University of the Western Cape, featuring a classical building with columns and a pediment, with the text "UNIVERSITY of the WESTERN CAPE" below it.

❖ What are the main factors taken into considerations when granting a large extract to a person for commercial purposes?

- Do you have a mechanism to insist on mandatory value-added processing in your own country?.....
- Do you negotiate supply contracts?.....
- Do you just negotiate royalties or ensure sustainable harvesting?.....

4. What are your ideas on the contribution of the Protection of Traditional Knowledge and the increase of Investment in African Countries?

- Do you insist on mandatory value-added processing in your country?.....
- Do you insist on the need to have the whole of the industries dealing with the production of the same drugs, or on the basis of local company to produce the same under license, or establishing a subsidiary Industry in the country of origin of these genetic?.....

5. Are the contacts of benefit sharing forming part of public documents in your jurisdiction or they are just a private documents held in between the concerned community and the foreign companies which access the genetic resources and associated knowledge?



6. Do you have a set of minimum benefit sharing to grant to the local community that has any contribution in any of your medicinal discoveries?

.....  
.....

Any other comments or contributions don't hesitate to write on the next page please!

Name.....  
Title.....  
Address .....

**ANNEXURE D**

GOVERNMENT NOTICE NO .....published on .....

**THE TRADITIONAL AND ALTERNATIVE MEDICINES  
ACT, 2002**

(NO 23 OF 2002)

**REGULATIONS**

(Made Under Section 55 (I) and (2))

**THE TRADITIONAL AND  
ALTERNATIVE MEDICINES (REGISTRATION  
OF MATERIA MEDICA) REGULATIONS, 2007**

**PART I**

**PLERIMINARY PROVISIONS**

- I. The Regulation shall be cited as the Traditional and Alternative Medicines (Materia Medica)Regulation 2007.
2. (1) These Regulations shall apply to all traditional and alternative medicines and related products  
(2) In case of proceedings before the Council, these Regulations shall apply to all traditional and alternative health practitioners and enrolled aides irrespective of whether or not any such traditional or alternative health practitioner is registered.
3. In these Regulations unless the context otherwise requires:" Act "means the Traditional and Alternative Medicines, Act, 2002;  
"Alternative Health Practitioner" means a person formally trained and has acquired knowledge, skills and competence in alternative medicine practices and disciplines as recognized international



"Category 1 Materia Medica" means extemporaneous medicines custom prepared by the health practitioner for the patient attending his/her Ki/inge:

"Category 2 Materia Medica" means traditional medicines with overwhelming ethnomedical information in the communities in which they are used. Scientific validations on their quality, safety and efficacy have been documented and therefore such products can be industrially manufactured and circulated in commerce;

"Category 3 Materia Medica" means new chemical entities that have been isolated from medicinal plants or preparations and on which the standard pharmaceutical research has been carried out. Such compounds can now be treated as conventional pharmaceutical products and thus regulated and commercialized as such,

"Category 4 Matcria Medica" means traditional medicines remedy that has been impolled from outside the WHO African Region. Since there is no known local African ethnomedical evidence available on them. they will require appropriate~ investigation on their sources. quality. safety and efficacy,

"Category 5 Materia medica" means" alternative medicine remedy tllal includes methods or processes used or curing or any preparations derived from plants. animals or mineral products that mayor may not contain chemical characteristics of such substances from which its derived that have the therapeutic effect in the intended individual and preparation of such a remedy follows the systems of alternative medical and discipline employed

"composition" in relation to materia m~dica means the ingredients which it consists. proportions and quantities in which those ingredients are contained

"container" in relation to materia medica regulated under this regulation, means a bottle, jar, box, packet, sachet, pumpkin guard or other acceptable instrument used to keep materia medica for human or animal use

"Council" means the Traditional and Alternative Health Practice Council established under section 4 of the Act;

"devices" means

"distributor" means

Killinge" means a basic traditional health facility which may provide consultancy and outpatient services;

"Label" means any tag, mark, pictorial or other descriptive matter, written, printed, marked or attached to a container of any materia medica or devices "leaflet" means and includes any written information related to materia medica or u<.:vit:<.:s

Materia medica means natural resources of medicinal value, semi processed or processed and finished for human healthy, animal or agriculture.

;"Minister" means the Minister for the time being responsible for health matters;

"owner" means any person legally registered as the owner of materia medica and or manufacturing facility for materia medica

"Raw or semi finished materia medica" means materia medica used as raw materials for preparation, processing and or manufacturing of traditional and alternative medicines;

"traditional health practitioner" means a person who is recognized by the community in which he live as competent to provide health care by using plants, animals, mineral substances and other methods based on social, cultural and religious background as well as on the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well being and cause of disease and disability

## PART II

### CONSERVATION AND MANAGEMENT

(1) The Council shall establish and maintain National medicinal plants data bank or compendium and prepare, keep and maintain a list of all medicinal plants;

(2) No person other than a registered practitioner, enrolled aide and local researcher shall be allowed to harvest medicinal plants in:

- quantity more than those consumed by family/household;
- quantities more than those required for his n practices per month
- quantities for the purposes of transpolling be)'and his district without the permit from the council
- no foreign person shall be al lowed to harvest medicinal plants for an) purposes without prior written permit from the Council

(3) No person shall sell raw or semi finished materia medica unless s/he is registered with the Council

5. (I) The Council shall issue guidelines prescribing the manner and nature of handling and transportation of materia medica and related materials;

(2) The materia medica shall be handled and transported in such a manner as shall observe safety, potency and quality of the raw materia medica;

(3) Materia medica shall be stored in such a manner as shall ensure safety, potency, quality and compliance of the guidelines as shall be issued by the Council;

(4) The materia medica shall be kept in a special room or area designed for that purpose and the room so designed shall be clean, dry and well ventilated to avoid moisture, overheating and pests;

(5) The Council shall issue guidelines prescribing shelf life for every medicinal plants, materia medica and any other related products;

(6) No materia medica shall be kept and stored for a period more than their shelf life

6. The Council shall conduct regular inspection to ensure compliance in respect of harvesting, handling, Storage, and storage facilities of materia medica and any other related products:

### PART III

#### PREPARATION AND PROCESSING OF MATERIA MEDICA

(I) The Council shall subject to these Regulations have power to categories various types of materia medica and related products;

(2) Types of materia medica and related products shall include;

- (a) Category I Materia Medica
- (b) Category 2 Materia Medica
- (c) Category 3 Materia Medica
- (d) Category 4 Materia Medica
- (e) Category 5 Materia Medica

8. ( I) Category I Materia Medica shall be extemporaneous medicines custom prepared by the health practitioner for the patient attending his/her Kilinge;

(2) Category 2 Materia Medica shall be well known traditional medicines with overwhelming ethno-medical information in the communities in which they are used and scientific validations on its quality, safety and efficacy have been documented and therefore such products can be industrially manufactured and circulated for commercial purpose:

(3) Category 3 Materia Medica shall be new chemical entities that have been isolated from medicinal plant or preparations and on which their standard pharmaceutical research has been carried out such compounds can now be treated as conventional pharmaceutical products and thus regulated by appropriate authority and commercialized under TFDA Act 2003;

(4) Category 4 Materia Medica shall be traditional medicines remedy that ha\c been prepared from materials or finished products imported from outside the WHO African Region,

(5) Category 5 Materia Medica shall be alternative medicines remedy that includes methods or processes used for curing or any preparations derived from plants. animals or mineral products that mayor may not contain chemical characteristics of such substances from which its derived that have the therapeutic effect in the intended individual and preparation of such a remedy follow the systems of alternative medicine: and discipline employed

(6) Category 2 and 5 of materia medica. the information on the label should include:

- (a) name and particulars of the medicine or remedy
- (b) ingredient used;
- (c) dosage form; ,
- (d) the name of manufacturer; and
- (e) batch number

(7) Raw or semi finished material medica shall be prepared, labeled and packed by practitioners in containers either modern or traditional to ensure safety, potency and quality;

9. The Council shall issue guidelines prescribing matters related to labeling, prescribing and dispensing of materia medica;

10. For the purposes of ensuring Consistent quality of preparation process and the product, every materia medica preparations, procedures and mixtures of a finished product shall be documented;

**PART IV  
REGISTRATION OF  
MATERIA MEDICA**

II. Save for extemporaneous materi.medica, all materia medica shall not be used any manner whatsoever unless registered by the Council;

12. ( I) **A person** who is desirous of his materia medica to be registered by the Council shall fill the application form and submit to the council

(2) The application forms shall be as set in the First Schedule to these Regulations; (3)

The application made under sub-regulation (I) shall be accompanied by:-

- (a) a certified copy of a certificate of registration of a practitioner;
- (b) a certificate of toxicological analysis and or tests;
- (c) statement as to the assessment of efficacy;
- (d) statement as to the clinical evaluation;

(4) Application for Registration of materia medica shall be approved by the Council subject to payment of fees as prescribed by the Council;

(5) The Council shall as quickly as practicable and after having been satisfied as to safety, potency. quality and compliance to these Regulations register the material

13. (I) The Council may cancel the registration of a materia medica and inform the owner or proprietor of the cancelled materia medica:-

- (a) if the materia medica is found to be toxic or has acute adverse reactions (b) if the materia medica is among the prohibited substance
- (c) if the materia medica after due research and tests is proved to have failed to cure the

intended diseases

(2) The Council shall publish in the Government Gazette cancellations of any materia medica

14. Person aggrieved by the decision of the Council under regulation 13 (2) of these regulations may appeal to the Minister

15. The Council shall keep and maintain a register of all registered materia medica and Publish the same in the Government gazette at least once per annum

## PART V MARKETING

16. (I) No advertisement for materia medica shall be made public unless scrutinized and approved by the Council;

(2) The Council shall issue PERMIT for ADVERTISING the registered materia medica after being satisfied that the provisions of these Regulations have been complied with;

(3) Any person who is desirous of advertising his materia medica shall apply for permit to the Council;

(4) The Council shall issue the advertising permit after payment of a fee as prescribed by the Council;

(5) Save for the producer of the materia medica, any person who intends to distribute materia medica for sale shall apply and get a permit from the Council;

17. (I) No person shall undertake large scale production and marketing of materia medica unless he is registered by the Council;

(2) Application for Registration 'of large scale production and marketing of materia medica shall be in the form as provided in the schedules to these regulations;

(3) The Council shall issue the permit after payment of fees as prescribed by the Council:

18. (I) No person shall export and or import materia medica unless he is registered as such by the Council:

rf} Application for Registration shall be in the form as may be set out by the Council;

(3) The Council upon liaising with relevant authorities shall issue export and import permit after payment of the export and import fees as shall be prescribed by the Council:

19. The Council may revoke or cancel any such permit where the holder of the permit contravenes any of the provisions of Regulations on marketing;

20. Any person aggrieved by the decision of the Council under regulation 16. 17, 18 and 19 of these regulations may appeal to the Minister;

21. The Council shall keep and maintain a register of exporters. importers and distributors of materia medica and related products;



22. (I) Every application for registration and license to conduct a research shall be submitted to the Council

(2) No person shall conduct research on materia medica unless he is recognized by the National Institute for Medical Research;

(3) Where an applicant is non citizen the application shall abide by rules and regulations prepared by National Institute for Medical Research, Commission for Science and Technology and Tanzania Food and Drug Authority. However, the Council may advise to stop research if it contravenes with these regulations;

(4) No person shall conduct research on matters other than those indicated in the license ; .

(5) Any research permits application on materia medica involving or in collaboration with Traditional and Alternative Health Practitioners shall be accompanied by a memorandum of understanding;

(6) The Council I shall satisfy itself f that the memorandum of understanding safeguards

the interests of Traditional and Alternative Health Practitioners, the Council and the Country;

(7) The Council may reject to offer the research permit if it is not satisfied with the memorandum of understanding;

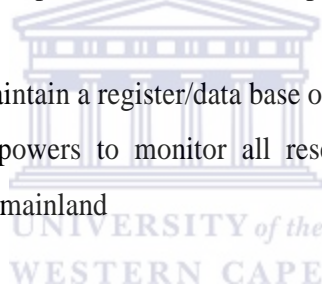
(8) There shall be a representative from the Council and Traditional Medicine Section in the Directorate of Hospital Services to the National Ethical Clearances Committee under the National Institute for Medical Research;

(9) There shall be a copy to the Council of the Council of the ethical clearance for all research related to materia medica;

(10) Every application for research permit shall be accompanied by a fee prescribed by the Council;

(11) The Council shall keep and maintain a register/data base of research on materia medica;

23. The Council shall have powers to monitor all researches on materia medica in the Country: in this case Tanzania mainland



## PART VII

### PROTECTION OF INFORMATION

The Council shall not disclose to third part information related to the Council

- (a) Botanical and biological composition of the materia medica and related products;
- (b) efficacy and active ingredients;
- (c) chemical composition;
- (d) methodology of preparation or preparation and processing of materia medica;
- (e) purity test and clinical evaluation
- (f) **information related to healing and treatment ;**

Unless agreed by the owner of the registered materia medica



25 (I) The Council shall protect the intellectual property rights of the founders and owners of the registered materia medica:

(2) No person other than the owner shall prepare, process, sell and or advertise for sale any registered materia medica unless he is authorized in writing by the owner;

(3) No person shall conduct research on any processed materia medica without prior written consent of the owners:

## P ART VIII OFFENCES AND PENALTIES

26 (I) Any person who intentionally gives false information to the Council as [O safety, potency and quality of the materia medica and other related material commits an offence and on conviction be liable to a fine not exceeding five hundred thousands shillings or to imprisonment for a term not exceeding six months or both;

(2) Any person who harvests, prepares or processes any materia medica without being registered by the Council commits an offence and on conviction be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding three years or both;

(3) Any person who harvests quantities more than those consumed by family/household without the permit from the council commits an offence and O:1 conviction be liable to a fine not exceeding one hundred thousands shillings or to imprisonment for a term not exceeding six months or both:

(4) Any person who harvests quantities more than those required for his/her own practices per month without the permit from the council commits an offence and on conviction be liable to a fine not exceeding two hundred thousands shillings or to imprisonment for a term not exceeding twelve months or both;

(5) Any person who harvests quantities '1'01' the purposes of transporting beyond his/her district without the permit from the council commits an offence and on conviction be liable to a fine not exceeding five hundred thousands shillings or to imprisonment for a term not exceeding two

years or both.

(6) Any foreign person who harvests medicinal plants for any purposes without prior written permit from the Council commits an offence and on conviction be liable to a fine not exceeding five millions or to imprisonment for a term not exceeding five years or both;

(7) Any person who advertises any materia medica without the approval of the Council ) commits an offence and is liable on conviction to a fine not exceeding three hundred thousands shillings or to imprisonment for a term not exceeding six months or both:

(8) Any person who advertises

(a) any counterfeit materia medica,

(b) sub-standardized materia medica,

(c) false label materia medica or

(d) contravenes any other provision of these Regulations,

commits an offence and is liable on conviction to a fine not exceeding three hundred thousands shillings or to imprisonment for a term not exceeding six months or both;

(9) Any person who sells or exposes for sale any un-registered materia medica or materia medica whose registration has been cancelled shall commit an offence and liable to on conviction to a fine not exceeding five hundred thousand shillings or to imprisonment for a term not exceeding one year or both.

(10) Any person who contravenes the intellectual property rights of the of the founder and the owner of the registered materia medica, commits an offence and on conviction shall be liable to fine not exceeding five million shillings or imprisonment for a term not exceeding three years or both.

**REFERENCES:****CONVENTIONS:**

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