Department of Law
Spring Term 2017

Master Programme in Intellectual Property Law
Master’s Thesis 30 ECTS

Title: “Protection of Traditional Medical Knowledge in the Patent System: Is There Room?”

Author: Ruth Mulenga Sinkala
Supervisor: Kacper Szkalej
Acknowledgements

I extend my sincere gratitude to my supervisor Kacper Szkalej for his invaluable guidance and direction during the writing process. For his loving support throughout the writing of this thesis, I would like to thank my husband without whom the completion of this work would not have been possible. I dedicate this thesis to my husband, my parents and siblings and thank them for their input and continuous encouragement.
# Table of Contents

Acknowledgements ........................................................................................................... i
Abbreviations/Acronyms ..................................................................................................... v

## Chapter 1 – Introduction .............................................................................................. 1
  1.1 Introduction .................................................................................................................. 1
  1.2 Research Question ...................................................................................................... 2
  1.3 Delimitations ............................................................................................................... 3
  1.4 Method ........................................................................................................................ 4
  1.5 Materials ..................................................................................................................... 4
  1.6 Limitations of this Investigative Effort ..................................................................... 5
  1.7 Structure ..................................................................................................................... 5

## Chapter 2 – Understanding Traditional Medical Knowledge ........................................ 6
  2.1 Defining TK ................................................................................................................ 6
  2.2 Defining TMK ............................................................................................................ 7
  2.3 Rationale for Protection of TMK as Such ................................................................. 9
    2.3.1 Economic or Commercial Importance ................................................................. 10
    2.3.2 Protection Against Biopiracy and Misappropriation ........................................... 11
    2.3.3 Preservation ....................................................................................................... 12
  2.4 Conclusion .................................................................................................................. 13

## Chapter 3 – The Patent System and TMK Protection .................................................. 15
  3.1 Inherent Antagonistic Nature of TK and the Patent System ................................... 15
  3.2 Fundamentals of TMK vs Fundamentals of the Patent System ............................. 15
    3.2.1 Origins and Application ...................................................................................... 15
    3.2.2 Ownership ......................................................................................................... 17
  3.3 Current Framework for Patent Protection – The Harare Protocol ......................... 18
    3.3.1 Novelty ............................................................................................................... 18
    3.3.2 Inventive Step/Non-Obviousness ...................................................................... 19
    3.3.3 Duration of Protection ....................................................................................... 21
    3.3.4 Comments .......................................................................................................... 21
  3.4 Defensive and Positive Protection ............................................................................. 22
    3.4.1 Defensive Protection .......................................................................................... 22
      3.4.1.1 Documentation .............................................................................................. 23
      3.4.1.2 Disclosure ..................................................................................................... 24
      3.4.1.3 Advantage of Defensive Protection .............................................................. 25
### Abbreviations/Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHPR</td>
<td>African Charter on Human and People’s Rights</td>
</tr>
<tr>
<td>ARIPO</td>
<td>African Regional Intellectual Property Organisation</td>
</tr>
<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
</tr>
<tr>
<td>IPR</td>
<td>Intellectual Property Rights</td>
</tr>
<tr>
<td>OAPI</td>
<td>Organisation Africaine de la Propriété Intellectuelle</td>
</tr>
<tr>
<td>PACRA</td>
<td>Patents And Companies Registration Agency</td>
</tr>
<tr>
<td>PCT</td>
<td>Patent Cooperation Treaty</td>
</tr>
<tr>
<td>THAZ</td>
<td>Traditional Healers Association of Zambia</td>
</tr>
<tr>
<td>TK</td>
<td>Traditional Knowledge</td>
</tr>
<tr>
<td>TKDL</td>
<td>Traditional Knowledge Digital Library</td>
</tr>
<tr>
<td>TMK</td>
<td>Traditional Medical Knowledge</td>
</tr>
<tr>
<td>TRIPS</td>
<td>The Agreement on Trade-Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>UDHR</td>
<td>Universal Declaration of Human Rights</td>
</tr>
<tr>
<td>UNDRIP</td>
<td>United Nations Declaration on the Rights of Indigenous people’s</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WIGC</td>
<td>WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore</td>
</tr>
<tr>
<td>WIPO</td>
<td>World Intellectual Property Organization</td>
</tr>
</tbody>
</table>
Chapter 1 – Introduction

1.1 Introduction

Traditional knowledge (hereinafter TK) is a vital component of the lives and wellbeing of many traditional communities\(^1\) or groups worldwide. The value of TK extends to numerous aspects of life including the health sector. In Africa, up to 80% of the population use traditional medicine or employ medicinal use of indigenous plants.\(^2\) Although TK in the medicinal use of plants (Traditional Medicinal/Medical Knowledge, hereinafter TMK)\(^3\) is applied extensively in the traditional community set up, it is evident that the use of adaptations of traditional medicines is becoming ever popular.\(^4\) TMK has therefore become the basis of much research, development and technological advancement in developing conventional drugs in the pharmaceutical industry which are eligible for patenting whose active component or key healing property is based on traditional medicine. Patents are obtained by researchers and companies for inventions based on TMK and this is often done without any acknowledgement or compensation flowing back to the traditional communities. Significant amounts of money are generated from these inventions; for example, the market for herbal medicine is growing rapidly with current estimates running up to 60 billion US dollars, and by the year 2020, the market is expected to reach a total of 5 trillion US dollars.\(^5\)

The obvious and increasing value of TK in the context of medicinal developments has prompted an increased interest in the protection and preservation of TMK. The knowledge possessed by traditional communities in the field of the medicinal use of plants draws particular attention to the protection of TMK. Presently, despite the varied biodiversity in the form of medicinal plants possessed on the African continent and the growing medicinal plant trade; exports of medicinal

\(^1\) In this thesis, the term “traditional community” and “local community” will be used interchangeably. These terms shall encompass any local community or tribal or indigenous or cultural group who hold some traditional medical knowledge. The terms local or traditional community are broader and all-encompassing and shall not be construed to exclude any indigenous or cultural or other unique groups possessing or capable of possessing TMK.


\(^3\) This analysis uses the concept of TMK rather than concepts of indigenous medical knowledge or ethnobotany because traditional medical knowledge encompasses indigenous medical knowledge while the reverse is not true hence the concept of TMK is more inclusive; See WIPO Report on Fact Finding Missions on Intellectual Property and Traditional (1998-1999) at p. 23.


\(^5\) Alam & Alikhan, 2008 at p. 20.
plants from Africa contribute little to the overall trade in natural medicinal products globally and generally only revolve around plant species of international interest that are indigenous to Africa. The lack of awareness of the commercial and economic value of TMK in Africa accompanied by the prevailing attitude towards TMK creates an unconducive environment for traditional communities to derive the greatest benefit from TMK and enable this vital branch of knowledge to reach its full potential.

Weaknesses in existing laws and policies or the complete absence of laws and policies towards TK makes it difficult to protect it in Africa. However, the African Regional Intellectual Property Organisation (ARIPO) began focusing on the protection of TK formally in August 2000 during which time the organization decisively opted to develop a coordinated strategy to become fully participative and actively engaged in the newly formed World Intellectual Property Organisation Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIGC). These efforts culminated in the formulation of the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the framework of ARIPO in 2010. The Swakopmund Protocol has since been ratified by some member states and remains a unique African initiative for the protection of TK.

TMK is knowledge worthy of protection, however the pertinent question which this thesis seeks to explore is whether the patent system is best suited to protect African TMK or whether protection should be sought outside the traditional patent system. It further seeks to explore the operation and scope of the protection offered by the Swakopmund Protocol and to peer into the operation of the Protocol at a national level using the Republic of Zambia as a case study.

1.2 Research Question

The research question sought to be answered is;

8 Hereinafter referred to as the Swakopmund Protocol.
9 Hereinafter referred to as Zambia.
“Is the patent system best suited to protect African TMK or should protection be sought outside the traditional patent system?”

1.3 Delimitations

The subject matter of this thesis will be limited to TMK. This means TK in the field of plants or flora which possess medicinal properties whether as a contributory ingredient, as components of an entire cure or treatment or as the whole independent active ingredient which is known by traditional communities by virtue of their cultural heritage. TMK for purposes of this paper will include traditional herbal medicines. Therefore, TK in the form of traditional cultural expressions, folklore and any other type of TK which does not form part of the above-mentioned definition will not form part of the analysis. Although the focus of the research is TMK, continuous reference will be made to TK itself as many principles relating to TK in general have extended application to the specific category of TMK.

For present purposes, only the area of patents in intellectual property law will be addressed. The main concern of the study is to explore the flaws or merits of the patent system in the African context by means of the Harare Protocol on Patents and Industrial Designs within the Framework of ARIPO in relation to the potential protection which could be provided for TMK. Consequently, this paper will not comment on the suitability or unsuitability of other areas of intellectual property law such as copyright and trademarks for the protection of TMK. These fields may be mentioned in various contexts in the paper however, a detailed analysis of these separate branches of intellectual property law will not be undertaken.

Geographically, the focal point will be Zambia on account of the rich biodiversity possessed and the gross underutilization of TMK by traditional communities in the area. The domestic legislation of Zambia, particularly, the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act of 2016 will be examined as Zambia will serve as a case study. The emphasis will be on scrutinizing this instrument and zooming in on key aspects as perceived by

11 Hereinafter referred to as the “PTK Act”. 
the author. It must be noted that for purposes of exemplification or illustration reference will be made to other African countries.

The research will also cover another regional intellectual property instrument being the Swakopmund Protocol under the umbrella of ARIPO and an international instrument being the 1992 Convention on Biological Diversity\textsuperscript{12}.

The paper will also explore protection for TMK potentially outside the patent system including issues of defensive protection, positive protection and the utilization of suis generis systems and the human rights system.

1.4 Method

The research methodology includes both desktop and field research. Existing literature is used as a reference point to gather information on the subject matter. The research involves significant use of the legal dogmatic method in which existing legislation and instruments at national, regional and international level are appraised and critiqued. Interpretation of these various pieces of legislation is made following detailed reading and analysis.

Qualitative data collection equally plays a significant role in the research. The use of open-ended questionnaires and unstructured interviews is employed to enable detailed responses to be given by interviewees being representatives of larger organizations such as the Traditional Healers Association of Zambia\textsuperscript{13} and the Patents And Company Registration Agency\textsuperscript{14}.

1.5 Materials

The materials used in carrying out this research include both printed and electronic material. The use of national statues, regional instruments and international instruments is critical in this research. Specifically, the national legislation of Zambia viz the PTK Act, the Harare Protocol and the Swakopmund Protocol being regional instruments of ARIPO and the CBD as an international instrument. Scholarly works authored by various academics prove instructive in this research and present themselves in the form of several journal articles and writings. Published books are

\textsuperscript{12} Hereinafter referred to as the “CBD”.
\textsuperscript{13} Hereinafter referred to as the “THAZ”.
\textsuperscript{14} Hereinafter referred to as “PACRA”.
evaluated during this research and serve as credible information sources in establishing a background to the subject matter and document surrounding issues on the topic of TMK. Published studies, reports, records and reviews by organizations such as WIPO and independently commissioned organizations are a vital source of quantitative information and make a valuable contribution to the research by adding perspective and accuracy to the work. The use of the internet is invaluable and serves as a source of significant input into the research.

1.6 Limitations of this Investigative Effort

The issue being addressed in the study by its nature renders gathering of first-hand information challenging and requires some specialized knowledge. The use of scientific terms in the description of various medicinal plants used in TMK and the use of medical terms in describing healed illnesses requires some initiative in understanding. Additionally, the at times secretive nature of traditional groups possessing TMK results in a reluctance to discuss various issues and a desire to remain anonymous on the part of informers from the THAZ. Furthermore, it is challenging to gain opportunities to interview relevant members of PACRA owing to their busy schedules and limited time. The time constraints on the study limit the number of individuals with whom direct interaction is possible in order to gain first-hand information.

1.7 Structure

Chapter one is an introductory chapter designed to clearly put the research into context by outlining the main issue to be resolved and the context within which the research is carried out. Chapter two will establish a foundation for an understanding of the key concepts of TK and TMK. Additionally, the rationale for protection of TMK will be explained in detail. The antagonistic nature of the relationship between TMK and the patent regime along with the current patent protection framework provided by the Harare Protocol will be explored in Chapter three. Defensive and positive protection mechanisms will be analyzed in the same chapter including the possible use of suis generis systems and the human rights system as methods of protecting TMK. Chapter four will scrutinize existing protective frameworks for TMK in the form of the CBD and the Swakopmund Protocol. Zambia will be presented as a case study in chapter 5 which will address the existing legal and social environment in the country in relation to TMK and the protection available for TMK domestically in conjunction with the Swakopmund Protocol. Chapter 6 will be the concluding chapter and will contain some final remarks and recommendations.
Chapter 2 – Understanding Traditional Medical Knowledge

2.1 Defining TK

TK is a broad concept and encompasses various aspects of knowledge held by a particular traditional or indigenous community. Owing to the inherently broad nature of TK as a concept it has eluded precise and universal definition. In spite of this, a fairly well-rounded idea of the general meaning carried by the phrase “traditional knowledge” can be derived from a number of international instruments, academicians and various scholars who have attempted to define the term.

TK has been briefly defined as “local know-how held by indigenous communities living in close contact with nature, that is unique to a culture”\(^{15}\). This definition perhaps owing to its brevity fails to adequately convey the full extent to which TK is a living and practical system.

An academician, Dr. John Mugabe describes TK as “the totality of all knowledge and practices, whether explicit or implicit, used in the management of socio-economic and ecological facets of life. This knowledge is established on past experiences and observation.”\(^{16}\) The definition offered by Dr. Mugabe reflects the diverse nature of TK and the practical role it plays in the lives of traditional communities. Additionally, it takes cognizance of TK existing in a practical form by referring to practices\(^{17}\) and highlighting the source of TK. The above definitions provide a general understanding of TK and act as an appropriate starting point. However, more detailed descriptions of TK and to a large extent what TK entails may be found in specialized international instruments\(^{18}\).

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) established in the year 2000\(^{19}\) describes TK as:

\[
\text{the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations,}
\]

\(^{15}\) Quinn, 2001, p. 293.
\(^{17}\) Emphasis is mine.
practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.

The above description of TK furnished by the IGC demonstrates its broad and inclusive nature. It is evident that TK as a whole is not limited to knowledge in the context of theoretical knowledge but is associated with practical skills, know-how and innovation. This knowledge system is an inherent part of traditional community life. TK is in effect more than a mere body of knowledge; it is a living and dynamic system, the operation of which is seen within traditional communities and beyond. Reference to a “specific technical field” in the quotation above demonstrates that TK does not lack in scientific or technological basis\(^\text{20}\) rather it is unique because it constitutes part of the customs and cultural traditions of the community which has developed and maintained it.\(^\text{21}\)

The importance of TK as an entire system cannot be overstated, however the focus of this paper is on TMK which is inherently an aspect of the broader TK system. It is therefore vital to hone in on a definition or accurate description of the meaning of TMK.

### 2.2 Defining TMK

TMK may be generally defined as a subset of TK “consisting of the medicinal and curative properties of plants in indigenous culture.”\(^\text{22}\) These plants are largely native and endemic plants that are traditionally used for healing various ailments\(^\text{23}\). It is medical knowledge resulting from intellectual activity in a traditional context. Thus, TMK in this context will be with reference to human health, healing and well-being. It will also encompass the prevention, diagnosis, improvement or treatment of illnesses\(^\text{24}\).

Just as is the case with TK in general, TMK is a combination of knowledge and skills hence is practical and dynamic. TMK is often applied to traditional medicine and involves the application

\(^{21}\) Gervais, 2005, p. 137.
\(^{22}\) Cardozo, 2012, p. 788.
of skills and knowledge based on experiences unique to different cultures, various theories and beliefs which are all directed toward the maintenance of health within the community.

It must be noted that normally TMK tends to be practiced outside of allopathic or conventional medicine. It is therefore vital to contrast the two medical regimes briefly. Conventional or allopathic medicine is the dominant medical regime in the developed world. It is based on the idea that diseases cause people to become ill and should be treated with drugs or surgery or both hence is operated using an evidence based approach. Therefore, conventional or Western medicine is centered around a medical health care system which involves health care personnel who have received professional training from some higher educational institution in the use and administration of pharmaceutical drugs to patients. In the conventional medical system, drugs administered have been the subject of research for long periods and have undergone formal medical testing and have a confirmed scientific basis prior to being made available to patients requiring treatment.

Traditional medical healthcare on the other hand differs in terms of origin, composition, administration and distribution. According to the WHO, traditional medicine systems can be categorized as either codified or non-codified. Codified systems are those which have been disclosed in writing in ancient scriptures and are fully in the public domain. Non-codified systems are those which have not been fixed in writing and often remain undisclosed by TMK holders and are passed on in oral traditions.

In the African context, attempts have been made to integrate the allopathic system with the traditional medical systems. To date a total of some African countries have established legal

---

25 Sanders, 1974, p. 497.
27 Davis, 2012, p. 5.
28 This statement reflects the general principle. The author acknowledges that there may be use of experimental medicine or medication that has not been approved by the relevant medical authorities which may still be in circulation or distribution by alternative means.
30 For example, the Ayurvedic system of medicine, the Siddha system and the Unani Tibb tradition in India are documented in ancient manuscripts.
frameworks for traditional medicine\textsuperscript{31} however, traditional medicine systems remain largely uncodified\textsuperscript{32} and undocumented.

The TMK regime although also designed to promote health and heal ailments is a culture based approach to healthcare.\textsuperscript{33} The holistic approach of TMK healthcare takes into account not only the symptoms of the disease but also psychological and sociological factors which may be involved and this is a key distinguishing factor of traditional medicine from Western medicine. TMK primarily involves medicinal uses of plants and traditional systems of medical diagnosis. Administration of medicinal herbs, plants or other genetic resources is done by traditional healers, local community elders and at times by community members possessing TMK\textsuperscript{34}. The focus is on the use of genetic resources which possess natural healing properties as a solution to ailments. Those involved in the administration of traditional medicines do not undergo any formal training as in the allopathic medical system, rather the knowledge they possess is transmitted orally from generation to generation\textsuperscript{35}.

It is clear that the allopathic medical system and traditional medical practice differ in fundamental ways. However, the growing importance and role played by TMK has attracted increasing levels of attention resulting in a lobbying for increased protection of TMK. This demand for protection is made based on a number of factors which will be explored in the following subheading.

2.3 Rationale for Protection of TMK as Such

The usefulness of TMK is undoubted as traditional medicines and therapies are increasingly being used outside the confines of strictly traditional cultures.\textsuperscript{36} TMK is therefore deserving of protection whether within the intellectual property regime or otherwise. In this section, three fundamental reasons have been identified by the author; being economic or commercial importance, protection against biopiracy and misappropriation and preservation.

\begin{itemize}
\item These include: Eritrea, South Africa, Uganda, Zimbabwe, Cameroon, Ghana, Nigeria, Mali and Tanzania; see Oguamanam, 2006, p.300.
\item Azevedo, 2017, p. 20.
\item Traore, Mobolanle & Akincole, 2016, p. 67.
\item Abott, 2014, p. 19.
\end{itemize}
2.3.1 Economic or Commercial Importance

TMK evidently has commercial value in the local communities from which it originates and other communities to which it is disseminated. Numerous pharmaceutical drugs have been formulated on the basis of TMK\textsuperscript{37} or have found their origin in TMK which formed the starting point for further research resulting in the development of a final conventional “drug” product. For example, the antimalarial drug quinine was isolated from the bark of Cinchona Trees\textsuperscript{38} which had long been used by the indigenous peoples in the Amazon for the treatment of fevers. The Sweet Wormwood plant\textsuperscript{39} was used by indigenous Chinese peoples in the treatment of fevers for thousands of years and was later identified by Chinese scientists as containing an active compound which served as a potent antimalarial drug.\textsuperscript{40}

The role played by TMK in ethnopharmacology has also drawn increased attention to its commercial significance. Ethnopharmacology is “the study of actions and properties of medicinal agents often derived from plants indigenous to populations or ethnic groups.”\textsuperscript{41} This interdisciplinary science introduced formally in the early 1990s initially focused much of it’s research on the chemical, biological and pharmacological sciences. However, in recent times, particularly from the year 2010 onwards, efforts have been made to pay more attention to the interdisciplinary nature of ethnopharmacology and the key contribution made by TMK to the science.\textsuperscript{42}

The use of TMK in these fields and others demonstrates the huge potential for commercial value held by TMK. Various industries have keen interest in and actively search for the time tested TMK and TK in general for pharmacological product development and other products which can be incorporated into the stream of commerce. Hence, protecting TMK has the potential to improve the economy of many developing countries by greater commercial use of their biological wealth and increasing exports of TMK related products. These products can become commodities which may be subject to exportation independently or as a component of larger on demand medicinal

\textsuperscript{37} Mposhi, 2013, p. 237.
\textsuperscript{38} Scientifically known as Cinchona officialinis.
\textsuperscript{39} Scientifically known as Artemesia Annua.
\textsuperscript{41} Elisabetsky & ETKin, 2009, p.220.
products. If utilized fully TMK can play a major role in enabling African countries to greatly improve their economies through exploitation of their own biological wealth.

2.3.2 Protection Against Biopiracy and Misappropriation

Biopiracy has become a serious issue for developing countries and indeed African communities possessing TMK. Biopiracy is the practice of commercially exploiting naturally occurring biochemical or genetic material, especially by obtaining patents that restrict its future use, while failing to pay fair financial compensation to the community from which it originates. The use of medicinal plant extracts naturally occurring in cultural communities in an unethical and inappropriate manner by employing intellectual property mechanisms in contravention of national regimes based on the CBD also constitutes an act of biopiracy.

The manner in which multinational companies have in many instances extracted traditional plants with medicinal value and the knowledge associated therewith from traditional communities and produced conventional medicines from which patents worth millions can be obtained without rechanneling or sharing the benefit with the cultural community which was the source of the knowledge has been described as “stealing the loaf and barely sharing the crumbs.” To date, reports have indicated that there are more than 30 cases of “biopiracy” by the western world from African biocultural resources. The biopiracy problem is a strong motivating indicator of the need for TMK protection in Africa. The genetic material on its own is useless without the knowledge of how to make medicinal use of it. Thus, fighting biopiracy and protection of TMK are inextricably linked. The fact that those involved in biopiracy are able to simply without authorization take the genetic material and apply TMK which they have accessed unlawfully and successfully obtain a patent which results in a huge monetary reward goes against the fundamentals of the patent system itself which is to reward creativity and invention. The African continent stands to lose huge benefits from it’s biodiversity on account of a lack of legal protection

---

44 Or non-financial compensation.
46 Mgbeoji, 2014, p. 300.
47 Said by Dr Tewolde Berhan Egziabher, a leading expert on the topic at the Institute for Sustainable Development in Ethiopia.
against biopiracy which inevitably involves the use of TMK\textsuperscript{50} hence there is an urgent need for a protective mechanism in this regard.

2.3.3 Preservation

An African proverb states that “when a knowledgeable person dies, a whole library disappears.”\textsuperscript{51} Owing to the very nature of TMK being that it is transmitted orally from generation to generation and is dependent on the existence of the natural environment and biological resources; it inherently becomes more susceptible to loss. Thus, the protection of TMK is vital to ensure its preservation. In this context preservation is threefold. It encompasses preservation in the sense of avoiding actions that may erode traditional medicinal resources (biological component), avoiding actions which may disrupt or negatively affect the cultural lifestyle of the source communities (where the knowledge emanates) and documenting TMK itself.

The first two aspects of preservation find support in some international instruments. Article 1 of CBD states that a key objective is the “conservation of biological diversity.” The United Nations Declaration on the Rights of Indigenous people’s (UNDRIP) in Article 8(1) explicitly provides for the right of indigenous people not to be subjected to forced assimilation or forced destruction of their culture and in Article 8(2) creates a positive obligation on states to guarantee that right. The preservation and enabling of an undisrupted cultural oriented lifestyle for indigenous people’s is also seen in Article 9 of the UNDRIP which vests indigenous peoples with the right to live in accordance with community traditions and customs free of discrimination. Abiding by the provisions of the aforementioned instruments theoretically contributes to preservation in the first and second sense as discussed in this paragraph.

Preservation in the third sense however in the African context is not common place. The documenting of TMK among local communities can provide a framework for the maintenance and preservation of knowledge acquired over generations hence overcoming the problem of loss of knowledge as described by the African proverb in this subheading. The indigenous languages used to pass on TMK are not as widely spoken as they may have been in the past and younger generations may not be interested in receiving this TMK which is orally transmitted. It must be understood that documentation of TMK for purposes of preservation although a positive step is

\textsuperscript{50} (Accessed 20 March 2017) http://www.news24.com/Africa/Features/Focus-on-biopiracy-in-Africa-20020830
not without risks. In spite of this, some countries have undertaken documentation of TMK such as India by means of the Traditional Knowledge Digital Library (TKDL).

Preservation of TMK is not only in the interest of local communities from which the knowledge originates, but also operates in the interest of non-traditional communities which stand to benefit from the numerous advantages which TMK offers modern society. In 2002, the World Health Organisation (WHO) launched its first ever comprehensive traditional medicine strategy designed to encourage among other things the documentation of traditional medicines and remedies. Furthermore, documenting of TMK may function as a starting point for the integration or fusion of allopathic medicines and traditional medicines on an equally beneficial basis.

2.4 Conclusion

The meaning of TMK and the need to protect it as has been discussed in this chapter is an issue that has gained global appreciation. Although each rationale for protection discussed is important, it is the view of the author that in a practical sense the element of commercial and economic importance is the most fundamental and feasible. This view is held because of the huge potential possessed by TMK to impact the economies and commercial systems of African countries. The other rationales forwarded particularly that of preservation may lean more towards the sentimental aspect of the situation in the sense of protecting against loss of cultural practice. The value of TMK from a cultural perspective may not be appreciated by groups outside the traditional communities. However, the commercial potential of TMK is likely to draw attention of stakeholders such as governments and external investors who in reality have the power to affect change and to play a key role in enabling lawful exploitation of TMK.

Furthermore, the commercial rationale which recognizes the economic value of TMK would be the basis on which local communities gain some reward from exploitation of their knowledge while it is further developed by pharmaceutical companies and researchers for the benefit of the wider

52 These risks and disadvantages will be explored further in the proposals chapter 3 of this thesis.
55 Haider, 2016, p. 349.
community. The lives of TMK holders, pharmaceutical industries and the face of medical treatment in general could be changed drastically if the proper view of TMK is adopted. These possibilities prompt one to address the question of how such protection should be granted.
Chapter 3 – The Patent System and TMK Protection

There has been much discourse on whether the IPR system is the best suited mechanism through which protection can be granted for TK. In this chapter, the analysis will focus on the propriety of the patent system as a candidate for the protection of TMK. Further the chapter will examine alternative TMK protection mechanisms and their possible effectiveness.

3.1 Inherent Antagonistic Nature of TK and the Patent System

The choice of the patent system as a focal point is based on the premise that by and large, the products of TMK whether in the form of herbal based products for health and wellbeing or pharmaceutical drugs the active component of which is based on African TMK; are protected or attempted to be protected through obtaining of patents\(^5\)\(^6\). The patent system has in a sense been a tool of oppression to the protection of TMK because allopathic pharmaceutical drugs formulated on the basis of unlawfully obtained TMK have been capable of being granted patent protection\(^5\)\(^7\). In spite of this it is necessary to analyze whether the patent system can be turned around and used as a tool for the protection of TMK to the benefit of its holders and the TMK system in itself.

3.2 Fundamentals of TMK vs Fundamentals of the Patent System

The fundamental principles on which the patent system is based are inherently divergent from those on which TMK systems are based. For present purposes two aspects will be assessed, that is, the origins and application of the system as one aspect and ownership as another.

3.2.1 Origins and Application

The origins of the formal patent system can be traced to Europe. Fillippo Brunelleschi, a 14\(^{th}\) century Venetian architect laid the foundation for the patent system by securing the right to commercial exploitation of his invention\(^5\)\(^8\). The history of the patent system reflects strategic accommodation in various disciplines including chemistry, life sciences, information technology, business methods and communication technology. These disciplines were and continue to be

\(^{56}\) Feifei, 2008, p. 8.
^{57}\) Crespi, 1995, p. 439-441.
^{58}\) Mgebeoji, 2003, p. 405.
prominent in the Western world\textsuperscript{59}. During the age of industrialization in the West which coincided with the development of the patent system, developing countries lacked the political and economic strength to advocate for the protection of their traditional knowledge. Consequently, the patent system was developed by the technologically advanced states in accordance with their needs\textsuperscript{60}. It is not surprising therefore that the patent system appears inherently unaccommodating of TMK.

The international requirements for granting a patent are that the invention must be new or novel and involve an inventive step\textsuperscript{61}. The invention must also be capable of repetition by a person “skilled in the art”. The focus is on theoretical accuracy which would enable the outcome to mirror (to some extent) the “product” of the original inventor. In contrast, the origin of TMK in Africa cannot be traced to any one individual. Rather, the notion is inherently linked to the general existence of the tribal group or community. Therefore, the roots of TMK stretch as far back as generations of ancestors\textsuperscript{62} as new knowledge is integrated with existing knowledge. As highlighted in preceding sections of this thesis, traditional medicine adopts a holistic approach and views the healing of sickness as beyond physical only. The emphasis is not on theoretical accuracy but is empirical in nature. This means that the regime is based on practical experience and is results oriented. Repetitiveness is not a prerequisite. The aspect of repetitiveness is a potential stumbling block to protecting TMK within the patent system. TMK has often been criticized as rudimentary and lacking accuracy owing to the absence of use of conventional methods for measuring and combination of various ingredients to formulate African traditional medicines\textsuperscript{63}. It has been the subject of virulent attacks for lack of scientific methods\textsuperscript{64}.

Therefore, the two systems in the avenue of origin and application are divergent, incompatible and inherently antagonist.

\textsuperscript{59} This is not to say that such disciplines do not exist in their entirety in the African context rather the pioneers of these disciplines are found in the western world.

\textsuperscript{60} The original signatories of the Paris Convention on Industrial Property of 1883 were Belgium, Brazil, France, Italy, Netherlands, Portugal, Spain and Switzerland. The United Kingdom (UK) acceded to the instrument on 17 March 1884 and it came into force on 7 July 1884. This accession made the Convention law in the colonies of the UK at the time which included a number of African countries such as Zambia, Zimbabwe, Botswana, Kenya and others. At independence, Zambia for example issued a declaration for continued application in 1964 while others such as Botswana only acceded to the instrument many years following independence (acceded in 1998 after independence was gained in 1966). Hence the level of direct participation of these African colonies at the time of formulating the Convention is doubtful as the UK likely represented its own interests.

\textsuperscript{61} Article 27(1) TRIPS Agreement.

\textsuperscript{62} Flint, 2008, p. 8.

\textsuperscript{63} Stabinsky, 1996, p. 20.

\textsuperscript{64} Njoh, 2006, p. 145.
3.2.2 Ownership

Patent protection implies that the invention cannot be used commercially, made, distributed or sold without the express consent of the patent owner as indicated in Article 28(1) of the TRIPS Agreement\textsuperscript{65}. Ownership in the context of patents may be attributed to a person or persons whether juristic or natural. Therefore, the concept of ownership in the patent system is fundamental as the idea is to allow benefits to flow to the inventor to incentive further creativity.

On the other hand, in the context of TMK, the motivation for creation of medicinal knowledge is not centered around the potential rewards which could accrue to an individual per se, rather the dynamics of knowledge creation and acquisition are communal\textsuperscript{66}.

TMK is developed incrementally over long periods of time with input from various community members over the generations. Although TMK may in some sense stem from an individual who then passes on the information orally from generation to generation, its incremental nature entails that a number of community members contribute to the knowledge base over time. Therefore, the ownership of TMK is not attributable to any individual member of the community. Furthermore, in contrast with the implication of ownership in the sphere of patents which is that the owner of the invention can use the invention to the exclusion of others or allow third parties to use the invention in return for some financial benefit, TMK is shared freely among community members\textsuperscript{67}.

The explanation given in the preceding paragraph is not to say that African traditional communities have absolutely no concept of ownership or property rights. The concept of ownership and property rights is evident in different avenues of community life including inheritance and succession. Ownership in the context of TMK is existent however is communal in nature. Leaders and traditional healers lie at the forefront as custodians of TMK and in the case of the latter constitute the skilled personnel able to make practical application of TMK for the benefit of the community. Thus, the approaches adopted to the concept of ownership in the patent system and in the TMK system are divergent.

\textsuperscript{65}Colston & Middleton, 2005, p. 6.
\textsuperscript{66}Schüklenk & Kleinsmidt., 2006, p.124.
\textsuperscript{67}Dutfield, 2010, p.200.
3.3 Current Framework for Patent Protection – The Harare Protocol

The Harare Protocol is an instrument created within the framework of ARIPO. ARIPO is a regional intellectual property organization in Africa with nineteen member states designed to serve mainly Anglophone countries. The idea behind the creation of ARIPO was to enable English speaking African countries to pool resources in industrial property matters in order to utilize to the maximum available resources in member states and ensure effective protection of industrial property.

The Harare Protocol contains requirements for patentability of inventions in Section 3(10)(a) which provides that “Patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.” These three requirements may be referred to as patentability criteria and are at par with universally accepted patentability standards as reflected in Article 27(1) of the TRIPS Agreement.

3.3.1 Novelty

Section 3(10)(b) of the Harare Protocol provides clarity on the novelty requirement by stating that “An invention shall be considered to be new if it is not anticipated by the prior art.” The challenge presented by TMK is that the traditional medical remedies and formulas are not normally known by one person alone, rather the knowledge is considered the knowledge of the community. TMK may be common knowledge within a particular local community and may be practically in use and this could potentially be novelty destroying. According to the requirements set out in the Harare Protocol, the information will be known orally by community members thus an initiative to obtain a patent by the community may be unsuccessful owing to failure to fulfill the novelty requirement.

This aspect was illustrated by the Turmeric patent case which occurred in India. Turmeric is used not only for cooking but also in treatment of inflammations, liver disease, digestive disorders and as an antioxidant among other things. A patent was granted by the United States Patent and Trademark Office for the use of turmeric in healing wounds in favor of the University of Mississippi Medical Center. The granting of this patent was challenged in 1996 by The Council of Scientific and Industrial Research of India on the basis that it lacked novelty because the use of turmeric

68 Gervais, 2015, p. 63.
69 Agreement on Trade-Related Aspects of Intellectual Property Rights.
for the healing of wounds was age old in India hence undoubtedly formed part of the prior art. The presentation by the Council of Scientific and Industrial Research of India of turmeric as TMK was successful and the patent was revoked.

For those seeking to obtain a patent on TMK, there is huge potential for challenges to be encountered when proving novelty as illustrated by the turmeric case above. This would also be the case if local communities themselves sought to patent TMK under a community patent. It must be acknowledged that in many instances in the absence of an opposition being presented before the patent office it is common place for TMK patents which in reality lack novelty to be granted nonetheless. These patent applications slip through the cracks because of the lack of an efficient database system designed to document TMK which patent examiners can easily search through to determine the novelty of an application. Implementing such a system in Africa would reduce the number of patents for inventions related to TMK which are granted ignorantly in spite of in reality failing to meet the novelty requirement. However, the pertinent question is whether traditional or local communities would be willing to present or share their TMK for recording in these databases. Additionally, the possibility of the availability of TMK database libraries contributing to an increased potential for misappropriation of TMK with greater ease would also need to be addressed.

It is evident that the novelty requirement as crafted in the Harare Protocol which reflects international standards does not cater for the peculiar nature of TMK. In fact, it is submitted that following a strict interpretation of what constitutes prior art, all TMK forms part of prior art. This conclusion is drawn firstly based on the premise that TMK is not known by only one individual in a local community but is shared among community members. Secondly, because TMK is passed on from one generation to the next and is built upon as time elapses, it is not possible to sever one segment of TMK from the other as the knowledge is cumulative. Hence identifying the “novel” aspect of TMK from the combination of accumulated knowledge is not practical and would present challenges.

3.3.2 Inventive Step/Non-Obviousness

The second patentability requirement of an inventive step is expounded upon in Section 3(10) (e) of the Harare Protocol which explains that “an invention shall be considered as involving an

---

inventive step if, having regard to the prior art, it is not obvious to a person skilled in the art.” This requirement is also known as the non-obviousness requirement. In order to meet the non-obviousness requirement, the key factor is for the invention not to appear obvious to a person skilled in the art. The understanding of a person skilled in the art although not specifically defined by ARIPO itself can be derived from a neighboring organization being the Organisation Africaine de la Propriété Intellectuelle (OAPI).

The understanding of a person skilled in the art according to OAPI is a person with “ordinary knowledge and average ability. His level depends on the very nature of the technology; he is abreast of all the prior art and his knowledge of the state of the art is only what is expected of an average professional.” In the case of TMK, inventions presented for patent protection may either be purely based on the genetic resource to which TMK is the key or may be a combination invention where there is a fusion of both TMK and conventional or Western knowledge. Bearing this in mind a determination would need to be made on whether the fictitious person skilled in the art must be one who possess average knowledge, skill and ability in the realm of TMK and the other contributing area of technology. OAPI has suggested that where there exists a combination of technologies within an invention, the person skilled in the art is a “person who has ordinary knowledge in each of the relevant areas of technology.”

If the approach adopted to hybrid inventions by OAPI were to be applied in the case of TMK, this would require that this person skilled in the art must be skilled in the relevant background of TMK. The practical implication of this scenario is a skill requirement in TMK from various local communities. This would demand a means of integrating the teaching of TMK systems into substantive patent examination procedures to ensure that the TMK aspect in the hybrid invention is addressed.

The nature of TMK may render it difficult for examiners to access the basic skill to fulfill the person skilled in the art requirement and this creates the potential for requests of background information in the field of the particular TMK from applicants. In some instances, TMK may be scattered and hesitation to disclose certain aspects may cause a stumbling block.

Alternatively, the decision to ignore the TMK aspect in the examination of the person skilled in the art test would be to undermine a vital component of the patent system on which the reward aspect

74 Supra note 73.
is based. A fundamental pillar to the patent system is that the inventor has earned the rights to a monopoly because he or she went beyond what an ordinary member of the profession in the field of the particular technology would have done. The element of going “above and beyond” would be compromised if no examination of the TMK aspect was made which forms a part of the invention seeking to be patented. This principle would be applicable in even greater proportions if the invention was purely based on TMK without an element of external contribution.75

3.3.3 Duration of Protection

Assuming, but not conceding that TMK inventions could easily and successfully fulfill the patentability criteria, the next issue to be addressed would be the duration of protection. The period for which patent protection is granted per Section 3(11) of the Harare Protocol is 20 years. Granting protection for a limited time period to TMK is problematic owing to the intergenerational and cumulative nature of the knowledge76. TMK is used across generations hence logically, benefits should be derived across generations. The implication of time limited protection as offered by the patent system is that once the 20 year period elapses, the TMK would fall into the public sphere and be available for use as desired by third parties. Local communities view TMK as sacred and entrenched in their tradition and heritage while when seen from a purely patent perspective, it could appear that the sacred knowledge is being privatized and made open to the public domain. Once TMK is in the public domain, it is openly available even beyond where such knowledge is intended to be limited to within the local community77. The position of the African group highlighted in proposals made in 2002 and 200978 reflect the desire of the group as stakeholders in TMK to grant perpetual protection.

3.3.4 Comments

Following the analysis of the present patent protection framework in the Harare Protocol, it is abundantly clear that the patent system is unaccommodating of the peculiarities of TMK. The novelty requirement and the non-obviousness requirement may prove problematic in the context of TMK resulting in an undermining of the patent system which would lead to it losing its integrity

75 The question of industrial application as a patentability requirement is not problematic in the context of TMK. TMK has found application in numerous fields and industries such as medicine, pharmaceuticals and lifestyle drugs. See Semenya & Maroyi, 2013, p. 318.
76 OseiTutu, 2013, p. 80.
78 In response to the Decision on Intellectual Property, Genetic and Biological Resources, Traditional Knowledge and Folklore in Africa adopted by the Council of Ministers WIPO/GRTKF/IC/3/15.
in fields of technology which it is well suited to protect. The extent to which the patent system under ARIPO as it stands would require amendment in order to meet the needs of TMK would be extensive and tantamount to creating a new system altogether. Although the Harare Protocol is applicable to all contracting member states, member states themselves in their domestic legislation have in some instances sought to include disclosure requirements for inventions which to any extent incorporate TMK in order to identify local communities which are the source of the knowledge in an attempt to prevent misappropriation. Additionally, the protection offered in the patent system is for a fixed or finite period of time and this is entirely unsuitable for the TMK system. Therefore, it is submitted that to insist that TMK receive protection from the patent system is impractical owing to the difficulties which would be encountered in meeting the patentability requirements and the limited time period for which protection is offered. It is therefore appropriate to analyze alternative protection systems for TMK.

3.4 Defensive and Positive Protection

Generally speaking, any strategy to protect TMK within or outside the mainstream intellectual property law system can be categorized under defensive or positive protection. The nature of these two types of protection will be explored and the possible effectiveness of each system in protecting TMK will be examined.

3.4.1 Defensive Protection

The notion of “defensive protection” is derived from the root word “defend” which literally means to “resist from attack or protect from harm”. According to WIPO, when applied to TK “defensive protection” refers to measures aimed at preventing the acquisition of IPRS over TK by parties other than the customary custodians of this knowledge.

The patent system poses the greatest threat to illegitimate exploitation of TMK. Numerous pharmaceutical companies and other organizations have obtained patents based on TMK and have benefited immensely without the knowledge or consent of the traditional communities who are the holders of this knowledge. For example, Thaumatococcus Daniellii locally known as

79 For example, under Kenyan Intellectual Property Law, Section 29 and Section 53(2)(a) of the Industrial Property Act requires applicants to disclose the invention in a clear and complete manner.


81 WIPO, 2008, p. 4.
Katemfe is a fruit bearing plant species from and native to West Africa (Ghana) used as a sweetener without any negative health effects. In traditional Ghanaian medicine, the leaf sap is also used as antidote against venoms, stings and bites. The root sap is used as sedative and for treating insanity. A gene has been cloned and used as sweetener for diabetics and a patent has since been obtained by Tate & Lyle (UK) and Xoma Corp (A US based pharmaceutical Company). The sweetener is 300 times sweeter than sucrose. No compensation or benefit share has been given to the people of Ghana. The Katemfe incident is merely one of many and it has been estimated that as of 2004, if African nations received only 2% of royalties for their contribution to pharmaceutical research resulting from TMK, they would be owed in excess of US$5 billion annually.

In order to prevent occurrences such as the Katemfe incident described above, defensive protection may be employed. The two aspects of defensive protection being documentation and disclosure will now be discussed.

### 3.4.1.1 Documentation

The requirements for patentability must be met for a patent to be successfully granted. The novelty and inventive step requirement are often where TMK inventions slip through the cracks as it were. The determination of whether the novelty and inventive step criteria have been met is based on prior art searches conducted by examiners. Reference is made to prior art to determine what information was available at the time of filing and relevant comparison is made with the invention sought to be patented. Regarding TMK, due to its nature, the information is not usually readily publicly available. Traditional communities may be secretive about their knowledge and even in cases where the traditional community makes no deliberate effort to be secretive, the knowledge is generally used and applied at a community level only. It has therefore been suggested by the WIPO IGC that records be kept of existing TK which includes TMK. This can be done by means of databases, registries and inventories.

In India for example, a TKDL has been compiled and largely comprises of information about traditional medicinal plants in India and other Indian TK. As at 2013, the database contained

---

82 Onwueme, Onochie & Sofowora, 1976, p. 110.
84 Lim, 2012, p. 12.
85 Carolan, 2016, p. 28.
86 Tong, 2010, p. 5.
knowledge obtained from “ancient Indian texts stored in 34 million A4 size pages and translated into five foreign languages – Japanese, English, Spanish, German and French.” The database is searchable and is now used by patent examiners to assess various patent applications. The effectiveness of the TKDL in India has been reflected in a study conducted in 2011 which showed a 44% decline in patent applications regarding Indian traditional medicine systems and medicinal plant preparations at the European Patent Office. In the African context, TK databases exist on a small scale and are largely not operated or compiled at a national level. In many instances, the databases are for purposes of academic research at university level and are not specifically designed to work in harmony with the patent system for purposes of defensive protection of TMK.

Documentation in the form of databases enables complete information to be stored and made accessible to patent examiners to ensure that TMK is considered fully as prior art in the determination of whether an invention involving TMK seeking to be patented genuinely fulfils the novelty and inventive step criteria.

### 3.4.1.2 Disclosure

Disclosure is a defensive protection mechanism which has been pushed forward by the CBD and the IGC. The introduction of a disclosure requirement would compel patent applicants to disclose the source or origin of their TK. This requirement would undoubtedly bring forward the true holders of the TMK thus contribute to ensuring that patents are not granted erroneously as often as they would be in the absence of such a requirement. The practical implication of disclosure however would not be merely to mention the origin or source of the TMK, rather it would be necessary to demand that the required procedure in obtaining the TMK has been followed and necessary agreements have been concluded. The disclosure requirement has been applied in different ways in various jurisdictions in patent law.

---

91 For example, TRAMED (Traditional Medicine Database) designed by the University of Cape Town is a database which attempts to compile traditional uses of various African plants based on existing literature and CESRIKI (Center For Scientific Research Indigenous Knowledge and Innovation) in Botswana; an initiative of the University of Botswana which aims to document Botswana’s TK systems by constructing a smart systems database in conjunction with 100 TK owners.
92 See document WIPO/GRTKF/IC/11/17.
For example, a full disclosure requirement has been introduced into the national laws of Egypt and India with various degrees of strictness or rigidity. Sweden has adopted a more lenient version of the disclosure requirement stating that patent applicants should disclose the origin of TK but are not required to disclose and that failure to disclose will not affect the patent examination or the validity of the issued patent\textsuperscript{93}. On the other hand, in South Africa the disclosure requirement is strictly enforced and failure to comply will result in invalidity or unenforceability of the patent at issue.\textsuperscript{94}

It is submitted that in order for disclosure to operate effectively as a defensive mechanism, the disclosure required should be mandatory and detailed. Thus, patent applicants would be compelled to disclose and be unable to obtain the desired patent without complying.

3.4.1.3 Advantage of Defensive Protection

i. \textit{Preservative:} The documentation of TMK as a component of defensive protection has a preservative effect. Owing to the volatile nature of TMK, documenting the information to whatever extent serves the purpose of creating a record of its existence thus making it less susceptible to complete loss.

3.4.1.4 Limitations or Disadvantages of Defensive Protection

Defensive protection is an appealing strategy to employ in the protection of TK, however, it is not a flawless mechanism.

i. \textit{Fails to Take into Account Oral Disclosure:} The documentation aspect of defensive protection enables recognition as prior art of disclosed documented TK. This approach fails to consider oral disclosure. In reality, TMK is usually transmitted and disclosed orally hence it remains possible for orally disclosed TMK to be misappropriated by third parties as evidence of oral disclosure may not suffice as novelty destroying in the patent application\textsuperscript{95}.

ii. \textit{Fails to Bestow Positive Rights:} Defensive protection serves to prevent third parties from acquiring unauthorized or illegitimate IPRs over TMK however, it does not bestow any positive rights on TMK holders. Granted, the disclosure requirement may compel patent applicants to identify TMK holders to some extent and in some cases to enter agreements

\textsuperscript{93} Section 5a Swedish Patents Decree (2016:580).
\textsuperscript{94} Wong & Dutfield, 2010, p.154.
\textsuperscript{95} WIPO/GRTKF/IC/6/8 Defensive Protection Measures Relating to Intellectual Property, Genetic Resources And Traditional Knowledge: An Update (March 2004).
with them for the use of their knowledge however it fails to empower TMK holders to take advantage of their rights in the strict sense. This limitation is a serious one because an underlying problem in my view is that TMK holders lack positive justiciable rights. There is therefore a need to create and confer the rights to properly exploit TMK to derive the maximum benefit from it.

iii. *Risks of Disclosure:* Disclosure results in the TMK being made available to the public to the extent as would be recorded in the databases. This is inherently risky because others may access the documentation which makes the TMK part of prior art and some may misappropriate the information from that point. Outsiders having access to the TMK can use its components to create a new patentable invention.96

iv. *Logistical and Practical Challenges:* The documentation aspect of defensive protection requires that effort be made in the form of time, research and financial investment in manpower and other resources in order to gather the TMK available from various parts of the state concerned with the view to compiling a comprehensive database. TMK is not always readily available hence there would be a need to go in search of it and interact with the various communities while simultaneously inviting traditional communities to come forward with their TMK for documentation purposes. However, owing to the communal nature of TMK and the various customs and cultures of traditional communities there may be some reluctance to share the TMK available even if it is for documentation purposes. This is a significant challenge which needs to be overcome. As with the case of India, it may be possible that there exist ancient manuscripts on which the TMK is documented but a majority of the African TMK systems are orally communicated and handed down hence the challenge remains present in the African context.

### 3.4.1.5 Criticisms of Defensive Protection

The components of defensive protection have come under criticism over the years. A key aspect which it has been claimed is ignored by disclosure is the fact that TMK may be common among several tribes97. This means that TMK may not always be exclusive to a particular territory but may have multiple origins. Therefore, the issue would be whether disclosure from only one traditional community or area of origin would suffice as full disclosure. A second criticism which

---

96 Gupta, 2005, p. 475.
has been levelled against the defensive protection strategy by some patent authorities is that the disclosure requirement finds no basis in patent law and merely serves to complicate the patent obtaining process further. It is submitted however that the disclosure requirement can easily be related to the need to conduct a thorough prior art search and to uphold moral rights of inventors. The concept of moral rights is key in the law of patents as acknowledgement of the inventor is necessary\(^98\) and the importance of these rights is evidenced by the fact that they are inalienable and accrue automatically.

### 3.4.2 Positive Protection

This type of protection entails TMK holders acquiring IPRs or other rights over their TMK.\(^99\) A positive protection system centers on vesting enforceable rights in the hands of traditional communities in order to enable them to actively protect their TMK, promote its use and derive some commercial benefit from it. It must be noted that the rights concerned in positive protection of TMK systems are by no means limited to rights acquired within the IPR regime such as patents in the strict sense. They could include assertion of rights by traditional communities in the form of contracts, sui generis systems\(^100\), trade practices, labelling laws, civil liability, customary laws and protocols.\(^101\)

#### 3.4.2.1 Advantages of Positive Protection

i. Benefits to Traditional Community for Exploitation: In the context of TMK, positive protection may be advantageous as a means of promoting active exploitation of TMK by the community actually holding the rights.\(^102\) This is in contrast with defensive protection which merely prevents exploitation by third parties. The possibility of benefits to be derived from the commercial exploitation of TMK by traditional communities themselves if properly taken advantage of and adequately utilized would result in socio-economic development for the community and would extend into benefits for the economy on a large scale. If a conducive environment is created in the form of adequately informed communities and representatives who hold the relevant expertise in the avenue of positive protection

---

98 Article 4ter of the Paris Convention for the Protection of Industrial Property, “The inventor shall have the right to be mentioned as such in the patent”.
100 Suis generis systems although an aspect of positive protection will be discussed separately in this chapter.
101 Gillespie, 2013, p. 517.
sought, traditional communities would be strategically positioned to derive real benefits from their TMK and convert these benefits into enterprises based on TMK.

ii. *Enables Legitimate Exploitation of TMK by Third Parties:* Positive protection vests positive enforceable rights to exploit TMK in the hands of the traditional community itself. This means that the traditional community is at liberty to allow authorized exploitation of TMK by third parties whether in the form of multinational corporations, scientists or researchers. As a result, third parties may use TMK as a basis for various inventions provided appropriate recognition, compensation and benefit systems are put in place. TMK in this way serves to benefit the wider community.

3.4.2.2 Limitations or Disadvantages of Positive Protection

i. *Participation Heavy:* It is submitted that positive protection is participation heavy for both traditional communities and governments alike. From the perspective of traditional communities, it requires that they actively come forward to acquire positive rights to protect their TMK. Asserting these rights may require certain procedures; for example, if the rights are chosen to be asserted within the IPR regime in the realm of patents, it requires that traditional communities fulfill the patentability requirements as set out in various instruments and domestic legislation. At this point, such traditional communities are likely to encounter the hurdles discussed previously regarding the inherently antagonistic nature of TMK and the patent system. Assuming rights are sought to be asserted in the form of trade practices or by means of civil liability, this would require some level of specialized knowledge on the part of the traditional community. In a practical sense, it is unlikely that such specialized knowledge is common place among African traditional communities hence in the absence of such knowledge, experts in the named fields would need to be engaged by traditional communities in order to represent them accordingly. This would entail monetary investments and actively searching for such experts hence drastically slowing the process of acquisition of protection and presenting an ineffective protection mechanism. The governments of the lands of the respective communities holding the TMK would also have a major role to play. Owing to the situation described above, it may fall on governments to actively encourage these traditional communities to assert their rights. This would demand committed participation in the form of reaching out to traditional communities and providing relevant expertise to enable them to assert these positive rights and remain alert to possible infringements. Presently, there is no guarantee that the relationship between traditional communities and governments is palatable as on some occasions governments themselves have been involved in the misappropriation of TMK
belonging to traditional communities thus governments and communities do not necessarily share the same views.\textsuperscript{103}

3.5 \textbf{Suis Generis Systems}

The term sui generis when directly translated from Latin means “of its own kind” or “in a class by itself”\textsuperscript{104}. From the literal translation, it is evident that a sui generis system for the protection of TMK entails a unique or different mechanism of protection outside the typical protection offered within the intellectual property system. Many authors have argued on the efficiency or inefficiency of the introduction of suis generis systems to protect TK. OseiTutu\textsuperscript{105} has disputed the utility of a sui generis system arguing that existing IPRs already overreach and that a sui generis system would increase costs and decrease access to TK. Verma\textsuperscript{106}suggests that a sui generis system will be required at national and international level in order to benefit TK holders holistically.

A sui generis system requires formulation of legal rules and regulations which are peculiar to the TMK system and as far as possible take into account the particular needs of TMK holders. Therefore, various elements ranging from general rules governing protection of TK including issues of ownership, third party use, benefit sharing and protection available to specific rules regulating rights accompanying rights and consequences of misappropriation must be included in a typical sui generis system. Hence the system must be complete within itself and serve as a unique protection regime.

3.5.1 \textbf{Criticisms of Suis Generis Systems}

The concept of sui generis systems has come under criticism by some because on many occasions the sui generis systems created are national in nature. Thus, the extent to which protection is extended remains limited to national borders\textsuperscript{107}. The argument is therefore that TMK remains vulnerable outside national borders and can be misappropriated from that point. However, in my view this problem can be overcome and this has been demonstrated by ARIPO who have developed a regional instrument which serves as a commendable illustration of a sui

\textsuperscript{103} Kene,2009, p.310.
\textsuperscript{105} OseiTutu, 2011, p. 147.
\textsuperscript{106} Verma, 2005, p. 805.
\textsuperscript{107} Dua, 2014, p. 120.
generis system designed to be responsive to the peculiar needs of TMK protection. The instrument is regional hence protection extends beyond national borders for signatory states. However, due to the nature of TMK it is suggested that an international suis generis regime must be developed likely under the umbrella of WIPO in order to extend protection for TMK and set a minimum standard for TMK protection.

The author is aware that the IGC have carried out composite studies in order to assess the possibility of development of an international suis generis protection system and have enlisted expert opinions from various countries globally including Zambia, Nigeria, Peru, Portugal and the United States\textsuperscript{108}, however no concrete conclusion or resulting instrument has come to fruition.

3.5.2 Merits of Suis Generis Systems

The most prominent advantage of a suis generis system is that it can be tailor made to suit the peculiar needs of TMK systems. Thus, the system from the onset is specifically designed for the protection of TMK. Suis generis systems enable the incorporation of principles from various international instruments and systems including the IP system to formulate the most advantageous legal rules and regulations in the context of TMK. The nature of suis generis systems also enable a consultative approach with the primary stakeholders being the traditional communities themselves. The use of an inclusive process and approach in the formulation of the suis generis system thus ensures a more receptive attitude on the part of traditional communities. Suis generis systems are a unique positive approach to protection and can be well formulated and effective as demonstrated by the Swakopmund Protocol of ARIPO in the African context.

3.6 The Human Rights System

The human rights system can also serve as a mechanism for the protection of TMK. TMK holders are by virtue of being human entitled to the benefits which accrue from the application of human rights. This includes some fundamental rights as reflected in the African Charter on Humans and Peoples Rights\textsuperscript{109}.

Article 1 of ACHPR places an obligation on member states to expressly recognize the rights duties and freedoms contained in the charter by adopting legislative or other means to give effect to said

\textsuperscript{108} Ncube, 2007, p. 70.  
\textsuperscript{109} Adopted in Nairobi June 27, 1981 entered into force October 21, 1986 hereinafter referred to as the “ACHPR”.

30
rights duties and freedoms. Undoubtedly, this places a positive obligation on the state to take appropriate measures to ensure the protection of rights and freedoms contained in therein\textsuperscript{110}.

The ACHPR in Article 14 guarantees the right to property. This undoubtedly includes intellectual property thereby entitling peoples to the protection of intellectual property rights. When read with Article 19 which creates a non-discrimination clause in stating that “all people shall be equal and enjoy the same rights and respect”, it ensures that traditional communities are not excluded from the protection to intellectual property guaranteed by ACHPR purely on the basis that they are a traditional community.

These provisions can thus be invoked to extend protection to TMK in the sense of unfair exploitation or unauthorized use of TMK and can be used as a reference point in obliging governments to take positive legislative or other steps in enforcing this protection.

The utilization of the human rights system goes beyond provisions in the African system. The possibility to protect TMK by means of human rights extends to the international platform as evidenced by Article 1 of the International Covenant on Economic, Social and Cultural Rights, 1966 (the ICESCR). It establishes “the right of self-determination, including the right to dispose of natural wealth and resources.” According to Posey, this implies the right to protect and conserve resources, including intellectual property on the part of traditional communities\textsuperscript{111}. The author agrees with the interpretation posited by Posey because TMK in itself is a resource and is valuable hence traditional communities should be vested with the exclusive right to decide on its use and disposal. The Universal Declaration of Human Rights\textsuperscript{112} (the UDHR) is another instrument which points to the right of traditional communities to derive benefit from their TMK in stating in Article 27.1 that “Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” and in Article 27.2 that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” This entails that traditional communities are entitled to derive benefits from their TMK and enjoy proprietary protection for it.

The global human rights system can therefore be applied for the benefit of TMK holders. The system is uniquely placed to grant strong protection to traditional communities owing to the powerful position occupied by human rights in the international legal system. Additionally, the

\textsuperscript{110} Mugabe, 1999, p. 10.
\textsuperscript{111} Posey & Sanchez, 1994, p. 110.
\textsuperscript{112} Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948.
broad nature in which human rights are framed enables broader protection for associated TMK for traditional communities.

3.7 Conclusion

Seeking protection for TMK in the patent system clearly presents challenges as the system ignores the nature of TMK hence fails to address its specific needs. The exploration of defensive and other positive protection mechanisms provides better opportunities for the protection of TMK. Defensive protection mechanisms are operable although as discussed in the limitations above require effort on the part of stakeholders. However, defensive protection mechanisms play a key role in protecting TMK from third party misappropriation. Positive protection outside the patent system is also fundamental to the protection of TMK as it serves the unique purpose of bestowing enforceable rights on traditional communities holding TMK with particular potential being held by sui generis systems as the most flexible branch of positive protection capable of being molded to suit the needs of TMK.
Chapter 4 – Instruments Peculiar to TMK/TK Protection

As demonstrated in chapter 3, the patent system as it exists is in no way designed to meet nor to adapt to the peculiar needs of the TMK system in a positive protection mechanism capacity. Therefore, chapter 4 will undertake an examination of two relevant instruments vital to positive protection of TMK in the African context. These are the CBD and the Swakopmund Protocol. It is submitted that these instruments are better suited to operate as a protective mechanism for TMK. The accuracy or inaccuracy of this viewpoint will be explored in this section through an analysis of the strengths and weaknesses of selected provisions in the instruments.

4.1 Convention on Biological Diversity

The CBD is an international Convention which mandates contracting parties to preserve and maintain knowledge, innovations and practices of indigenous peoples and local communities. It aims to promote the wider use and application of such knowledge with the involvement and approval of knowledge holders and to encourage the equitable sharing of benefits arising from this utilization. The key article in the CBD which makes specific reference to the protection of traditional knowledge is Article 8 (j). It requires that each contracting party “shall, as far as possible and as appropriate: Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices.”

According to McManis, the article demands that traditional knowledge be respected, maintained and preserved for the benefit of various stakeholders. It must be noted and it is the strong view of the author that in order to obtain an accurate understanding of the depth and breadth of Article 8 (j), the article must be read along with several other provisions contained in the CBD. For example, Article 10 (c) requires parties to “as far as possible and appropriate, protect and encourage customary use of biological resources in accordance with traditional cultural practices

---

113 Aguilar, 2001, p. 142.
that are compatible with conservation or sustainable use requirements.” This requirement is interlinked with the underlying objective of article 8(j). Adopting such a broad and holistic approach to the interpretation of Article 8(j) will result in a better understanding of its true meaning.

In order to assess the strength or weakness of Article 8 (j) and by extension its effectiveness, a detailed analysis of the article shall be undertaken by isolating various words and phrases and discussing the propriety and implication of the choice of words.

4.1.1 Weaknesses

4.1.1.1 “As far as possible and as appropriate”
Article 8(j) begins with the wording “as far as possible and as appropriate”. This opening phrase immediately creates an inherent weakness in the article. As described by Aguilar, there is a window left open to States to comply or not to comply with the guidelines which follow. In fact, the language used in those phrases may appropriately termed “permissive language” which entails that there is no strict positive obligation laid on the State to comply meticulously with the instructions which follow the statement regarding the protection of TK. In addition to being merely permissive, the phrase is extremely subjective. This conclusion is drawn on the basis of the absence of guidelines or definitions regarding what circumstances may constitute an “impossible or inappropriate” situation. It should be noted that the author should not be misunderstood as suggesting that an exhaustive list of all possible circumstances should be furnished stating when it would be possible or impossible to implement the requirements of Article 8(j) rather, perhaps an exemplification or description of what would qualify would suffice. Thereafter, interpretations could be made using the examples provided as a guideline.

4.1.1.2 “Subject to national legislation”
The phrase “subject to national legislation” included in Article 8(j) essentially leaves the responsibility of respecting, preserving and maintaining, ensuring equitable distribution of benefits with national legislation authorities. This requires national recognition of traditional communities and to some extent, an outward recognition of customary law systems. Therefore, if contracting

\[\text{\textsuperscript{115}}\text{ Emphasis added.}\]
\[\text{\textsuperscript{116}}\text{ Other relevant articles are Articles 14,16,17 and 18 of the CBD which address cooperation, exchange of information, development and benefit sharing.}\]
parties fail or neglect to take steps to have certain protective measures reflected in their national legislation as required by the CBD, this would hinder the implementation of this article.\textsuperscript{117}

It is vital to understand that the CBD was drafted with a view to implementation of the National Sovereignty Principle. This principle is reflected in Article 15(1) of the CBD wherein biodiversity is regarded as a resource of the State. Therefore, because of this principle countries now have the right to regulate access to their biological resources and the knowledge associated therewith. This right extends to making determinations on issues of benefit sharing and allocation.

The concept of ownership by the State of national resources is a positive development in the context of the developed-developing countries phenomena. The principle was forwarded by developing country governments to defend national interests against foreign developed country governments and transnational corporations. However, on a domestic level in the context of traditional communities, the concept of what really constitutes the “state” brings into question whether traditional communities have a true stake in the decisions made regarding the TK which they own.

Thus, vesting the rights in the state to carry out decisions regarding TK may not necessarily translate to these decisions being made in consultation with traditional communities. The manner in which the CBD places a considerable amount of influence on national legislation creates the potential for legislation to simply be made at a national level regarding TK which includes TMK without an obligation to consult the real traditional communities involved. The effectiveness of this provision is reliant on state sovereignty. It must be mentioned however that it has been argued by Wolfrum and Stoll that the article was crafted to deliberately improve the relation of states within local communities and indigenous or traditional communities within the same state.\textsuperscript{118} This viewpoint it is submitted is a long shot and is not reflective of realities obtaining on the ground. The applicability of the analysis of Wolfrum and Stoll is not guaranteed and is heavily dependent on a state adopting a consultative approach with traditional communities.

The principles espoused in the CBD can be enforced only when they are incorporated into the national legislation of signatory countries should they choose to institute them.\textsuperscript{119} In the absence

\textsuperscript{117} Corpuz, 2003, p. 33.
\textsuperscript{118} Anderson, 2016, p. 141.
\textsuperscript{119} McManis, 2012, p. 40.
of nationalization of these principles, they appear to become simply gestures of goodwill with no possible binding application.

4.1.2 Strengths

4.1.2.1 “Respect, preserve and maintain knowledge, innovations and practices”
The concepts of respect, preservation and maintenance referred to in Article 8 (j) are well chosen. All three ideas imply that action needs to be taken to grant TMK the recognition it deserves, to enable its continued existence and to maintain the integrity of the system. In my view the element of “respect” introduces a moral rights aspect into the discussion from an intellectual property law perspective. The relevant moral rights are the right of attribution, the right against false attribution and the right not to have TMK subject to derogatory treatment\(^{120}\). These three categories of moral rights have been deemed relevant because in the context of TMK they have proved to be the most problematic.\(^ {121}\) If understood in this way, Article 8 (j) effectively creates room for recognition of moral rights for TMK. The communal nature of TMK would demand that recognition of authorship for the knowledge not be granted to an individual community member per se but to the entire community.\(^ {122}\) This would entail that where pharmaceutical drugs are produced including a TMK element, this should be attributed accordingly.

4.1.2.2 “Promote their wider application with the approval and involvement of the holders of such knowledge”
This aspect of Article 8(j) indicates an inclusive approach towards TK. The requirement for approval necessitates effective communication between traditional communities and the state or state parties\(^ {123}\). Hence there is a possibility for the fusion of traditional medical treatment and mainstream allopathic medical treatment. This potential fusion must be considered in harmony with the objective to preserve and maintain TMK. The implication of such a harmonious consideration is that TMK need not be absorbed into mainstream medical treatment and lose its identity or sense of uniqueness as a treatment alternative, rather, it must be accorded the needed recognition and elements of it can be used to enhance and develop mainstream treatments or

\(^{120}\) Seville, 2016, p.115.
\(^{121}\) Ncube, 2007, p.59.
\(^{122}\) Antons, 2009, p. 358.
\(^{123}\) State Parties had been requested by the WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) to include representatives of local and indigenous communities in their delegations to promote consultation and effective communication and to facilitate full participation of indigenous groups in the meetings organized within the framework of the Convention- CBD Decision IV/9 Par 3-5.
pharmaceutical products and vice versa. Thus, the two systems can be mutually beneficial and as a result find a wider application.

The issue of approval has been translated to mean prior and informed consent\textsuperscript{124}, thus TMK holders are not to be viewed as mere vessels in the process of acquiring TMK but as active participants who essentially have the authority to accept or reject the gaining of access to and the distribution of their knowledge. This provision if used and applied effectively is designed to eliminate unauthorized access to TMK or access to biological material linked to TMK by those seeking to gain knowledge for commercial reasons or otherwise.

4.1.2.3 “Equitable sharing of the benefits arising from the utilization of such knowledge”

For the most part, industries use TMK and resources without asking for consent and without sharing the benefits of such exploitation with the indigenous or local communities themselves.\textsuperscript{125} Undoubtedly then, the introduction of a benefit sharing requirement in Article 8 (j) is a positive development. According to Aguilar, Article 8 (j) implies that researchers should pay for the TK made available to them and that they must maintain confidentiality of such knowledge if so required.\textsuperscript{126} This interpretation seems accurate in the view of the author because in practical terms, the reward gained by individuals and corporations who access TMK and put it to use in the pharmaceutical and other industries is largely financial or monetary. Thus, this financial reward gained must be shared with the local communities from which the TMK is sourced. Although the reward is largely financial, other benefits arising may be in the form of development of new medicines or treatments which include a TMK component. Such medicines should also be made available to the local communities from which the TMK originated\textsuperscript{127}. Therefore, both monetary and non-monetary benefits alike must be shared equitably.

An interesting aspect of the benefit sharing arrangement is the use of the word “equitable”. This indicates that mere sharing will not suffice. The sharing must be equitably done. The provision therefore serves a greater purpose than merely creating a sense of entitlement on the part of local communities, rather it entails active participation in negotiations in order to secure an equitable

\textsuperscript{124} Kalaskar, 2012, p. 10.
\textsuperscript{125} Lewinski, 2008, p. 369.
\textsuperscript{126} Aguilar, 2001, p. 243.
\textsuperscript{127} Some local communities may be apprehensive in terms of accepting treatments in the form of mainstream pharmaceutical drugs, nonetheless the newly developed drugs may be supplied to the country as a whole at a potentially discounted rate due to the role played by the traditional community in the development of the medication.
benefit share. The CBD contains no precise definition of equitable benefit sharing however a number of definitions have been suggested. According to the Union of Ethical Bio Trade, fair and equitable distribution of benefits involves reasonable and commensurate distribution of benefits to contributing communities arising from utilization of biodiversity and associated TK.¹²⁸

Therefore, it is proposed that equitable benefit sharing involves proportionality. The proportion of the contribution made by TMK from a local community to a subsequent final product should be considered. Thus, if a benefit from the final product will continue to accrue and increase in value, a simple once off payment as permanent compensation to a contributing local community would be inequitable. Rather, a more appropriate benefit sharing approach would be the making of ongoing payments, perhaps as a percentage of the earning of the discovered commercial product commensurate to the value of the contribution offered by TMK for as long as the benefit continues to accrue. The emphasis in this regard should be on rendering a corresponding and proportionate benefit to the community supplying the TMK.

Ideally, community members or elders as representatives of the tribe being the owners of the TMK should fully participate in negotiations; the workability of this idea is questionable. Those who seek to access and utilize TMK are usually highly educated researchers who are employed by huge multinational corporations, governments or well-funded research institutions. On the other hand, tribal community elders though knowledgeable in TMK and other aspects are not best placed to independently handle negotiations which have the potential to delve into the political arena involving benefit sharing. Therefore, in my view it is necessary to have neutral third party representatives involved in the negotiations to advise on various technical aspects. A consultative approach is needed in order to arrive at an arrangement which will serve the interest of the local community. The CBD in this regard lacks detail in terms of exactly how an equitable benefit sharing arrangement ought to function.¹²⁹

¹²⁹ The CBD Working group of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was in 2013 tasked with the development of more detailed and specific international guidelines regarding equitable benefit sharing; no guidelines or other mechanisms have been developed to date as the work is ongoing. See - http://www.benelexblog.law.ed.ac.uk/2014/07/08/benefit-sharing-and-traditional-knowledge-the-need-for-international-guidance/ (Accessed 01 May 2017).
4.1.3 Remarks
From the foregoing analysis, it is clear that Article 8(j) of the CBD possesses some inherent weaknesses. However, the intention of the Article and what it seeks to protect is well placed. Article 8(j) as read with corresponding provisions in the CBD encompasses at a general level the protection sought for TMK. The use of permissive language and heavy reliance on national implementation in the absence of detailed and specific guidelines as a rudder for national legislation is a huge flaw. Furthermore, the absence of an international instrument designed as an enforcement mechanism for the provisions of the CBD with binding consequences places it in a weaker position as the preferred protective mechanism for TMK.

4.2 The Swakopmund Protocol
The Swakopmund Protocol is a regional legal framework designed to address the protection of TK and folklore and provide a holistic view of African TK holders for purposes of legal certainty and management of their inalienable rights. Evidently, the Swakopmund Protocol is a sui generis system for the protection of TK. Therefore, it is not constrained by the limitations of patent law or other mainstream IPR regimes. It has been described as “a historic step for ARIPO member states and a significant milestone in the evolution of intellectual property.” The protocol begins by stating its purpose as to “protect traditional knowledge holders against any unauthorized exploitation of their rights; misappropriation, misuse and unlawful exploitation beyond their traditional context”. This purpose succinctly addresses the major problems faced by TK holders. In the analysis to follow, particular aspects of the Swakopmund Protocol relevant to TK holders have been selected and will be discussed in detail. The strengths and weaknesses will be explored accordingly.

4.2.1 General Observations

4.2.1.1 Terminology
The terminology used in the Swakopmund Protocol such as “local communities and traditional communities” is broad and encompasses a wider variety of groups which may possess TK unlike

131 Section 7 of the Swakopmund Protocol.
132 Supra, Section 1.1 (b).
the use of terms such as “indigenous” which considered in various contexts may have the effect of limiting which groups may qualify as TK holders. This is a commendable feature of the Protocol and reflects a desire to broaden the scope of groups capable of protecting their TK provided the requirements stipulated in section 4 are met.

4.2.1.2 Regional Approach

The Swakopmund Protocol adopts a regional approach to protection of TK. Section 24 in capturing the operation of the regional protection approach mandates that “eligible foreign holders of TK shall enjoy benefits of protection to the same level as holders of traditional knowledge and expressions of folklore who are nationals of the country of protection”.133 For TMK, this is commendable because in the African context, migration for various reasons is common place hence foreign groups may exist who hold TMK though not being nationals of the state in which they reside. Enabling such protection may motivate such groups to permit the exploitation of their knowledge without fear of differential or discriminatory treatment. Furthermore, this promotes the principle of non-discrimination and unified regional treatment thus setting the tone for regional cooperation and uniformity in protection awarded to TMK across the region.

4.2.2 Recognition of Peculiarities of TK

The Swakopmund Protocol is drafted in a manner which recognises and accommodates accordingly the peculiarities of TK as demonstrated in the aspects below.

i. Automatic Protection: Section 5.1 of the Swakopmund Protocol states that protection of TK shall not be subject to any formality therefore any knowledge which qualifies as TK134 is automatically entitled to protection. This approach is commendable and is in the view of the author entirely correct. The holders of TMK in Africa are in some cases isolated from mainstream society135 thus it is impractical to demand formalities as a prerequisite to granting protection because access to executing the formalities required could prove difficult for such groups. Additionally, formalities would likely involve the payment of various fees and registration paperwork which these traditional communities may not have

133 Ibid, Section 24.1 of the Swakopmund Protocol.
134 Per Section 4 of the Swakopmund Protocol; TMK undoubtedly falls within this category hence falls within the ambit of TK deserving of protection.
the capacity to execute unassisted. The Swakopmund Protocol in this regard remedies a flaw found in the patent system by eliminating the need for formalities.

ii. **Communal Ownership:** Section 6 in describing who the holders of TK are recognizes the concept of communal ownership. Express reference is made to owners being "local and traditional communities". This overcomes a further shortcoming of the patent system in that the patent system is centered on individual ownership and exclusivity.

iii. **Continued Use in the Traditional Context:** Section 11 enables continued use of TK in the traditional context without any legal implication despite issuances of licenses or other access agreement with knowledge seekers. This is in sharp contrast with the patent system which entails essentially grants the author a monopoly over the use of the invention. Unauthorized use of a patented pharmaceutical product amounts to an infringement of the rights which accrue to the patent holder. In the traditional medical context, this section is vital because TMK in traditional communities and other parts of the population is widely depended upon as the primary means of treatment. As a result, the right to health, life and self-preservation remains unaffected even with the existence of the Swakopmund Protocol.

iv. **Duration of Protection:** The duration of protection for TK if protection were sought under the patent system would be 20 years. Once the 20-year period has elapsed, the "invention" falls into the public domain. The provision of a fixed term of protection for TMK is not appropriate for its nature. The Swakopmund Protocol remedies this shortcoming of the patent system by granting protection to TMK holders in perpetuity according to section 13. This accommodates the essence of TMK as it is held by the "present owners and their descendants in perpetuity rather than for a limited period." It should be noted however that this does not apply where TMK belongs exclusively to an individual.

---

136 Section 6 also includes and recognizes the possibility of individual ownership of TK. This may occur but is not commonplace. If so, the element of proof resides in the community members recognizing that particular individual as the sole owner of the TK.


138 Article 33 TRIPS Agreement.

139 Olatokun, 2010, p. 121.

140 Individuals shall only be granted protection for 25 years under the Swakopmund Protocol.
4.2.3 Rights Conferred Upon TK Holders

i. *Authorization and Prevention of Exploitation:* Rightsholders have the exclusive right to prevent exploitation of TK without their prior informed consent and to authorize its use as noted in section 7\textsuperscript{141}. The definition of “prior informed consent” contained in the Swakopmund Protocol\textsuperscript{142} requires that complete and accurate information be provided to the concerned communities. Although some parties seeking to utilize TMK may come in good faith or *bona fide*, others may come with bad intentions or *mala fide*.\textsuperscript{143} Various local communities have different levels of exposure hence may be vulnerable. This is not to say that local communities lack intellectual capacity nor that they are incapable of representing their own interests. Rather, it is simply to take cognizance of the situation which obtains. Usually, parties who seek to benefit from or utilize TMK are researchers from multinational companies. Thus, there may be a language or other cultural barrier to direct communication with TMK holders. It is therefore submitted that to protect the interests of traditional communities and to enable genuine prior informed consent to be sought, translation services and an “educated” representative must be present to facilitate this communication. Appropriate evidence of the intended use of the TMK and various projections must be presented and fully disclosed during these discussions. Ensuring that such mechanisms are in order and available will empower communities to effectively exercise the right to authorization of use of their TMK.

ii. *Institution of Legal Proceedings:* In the event of unauthorized use of TK, Section 7.4 confers upon local communities the right to institute legal proceedings. In order to do so, some degree of knowledge and representation is necessary. Therefore, the protection of TMK goes beyond mere independent defense by the concerned local communities but requires the involvement of other parties with various levels of expertise to enable traditional communities to fully and effectively assert their rights\textsuperscript{144}.

\textsuperscript{141} Ibid Section 7.2.
\textsuperscript{142} Ibid Section 2.1.
\textsuperscript{143} West, 2012, p. 25.
\textsuperscript{144} The institution of legal proceedings by a traditional community is not unprecedented. The San opposed unauthorized use and commercialization of the “Hoodia cactus Plant”. The Hoodia plant had been used for generations by the San to suppress thirst and appetite or ward off hunger during long hunting trips in the Kalahari Desert. The San alleged bio-piracy and threatened legal action with the support of advocates and various NGOs. The parties were able to reach a mutual agreement and conclude a benefit sharing agreement. - Human Development Report. 2004, Chapter V, “Globalization and Cultural Choice”, Washington, D.C: UNDP, referenced in State of the World’s Indigenous Peoples, 2009, ST/ESA/328, at p. 75.
iii. **Moral Rights**: Moral rights are addressed in section 10 where the Swakopmund Protocol obliges persons to acknowledge the holders, source and origin of TK in a way that respects the cultural values of its holders. This section essentially deals with the right to recognition of the author(s) and is especially important as many aspects of TMK culminate in the development and production of pharmaceutical drugs, herbal products and alternative treatments in the absence of recognition of the role played by TMK in the development process. Such acknowledgement should be given “in a manner that respects the cultural values of its holders.” Therefore, by necessity, parties seeking permission or access to use TMK must to some extent be familiar with the culture of the traditional community from whom they seek knowledge. However, it is unreasonable to expect that all who seek to explore TMK be well versed in the culture of the local community hence a possible practical suggestion may be to insist that such ones gain basic knowledge of respectful cultural practice in the context of the TMK required.

iv. **Licensing Agreements**: The owners of TK have the right to conclude licensing agreements in writing for the use of their knowledge according to section 8 of the Swakopmund Protocol. The written document requirement creates the need to provide support to local communities in the form of knowledgeable neutral individuals capable of representing the interests of traditional communities in such licensing agreements. The issue of compulsory licensing which is a common feature of the patent system is regulated in section 12. It grants the State the mandate to issue a compulsory license where “protected traditional knowledge is not being sufficiently exploited by the rights holder” or where “the rights holder refuses to grant licenses subject to reasonable commercial terms and conditions” only in the interests of public health or public security in order to fulfil national needs. In my view, section 12 by creating a compulsory licensing provision demonstrates balance and a desire for the wider community to benefit from TMK and takes cognizance of the right to healthcare. Notably, the same section does not allow traditional communities to be taken advantage of when these compulsory licenses are issued rather makes provision for appropriate compensation to be given to the traditional communities concerned.

At this juncture, a fundamental question arises; does section 12 directly or indirectly create an obligation to exploit TK? In my view, an obligation to exploit TK has been created. Insufficient exploitation (provided the public health or safety requirement is met) constitutes valid grounds for issuance of a compulsory license. Effectively, the Swakopmund Protocol obliges traditional communities to exploit their TMK and this interferes, although for good reason, with their right to decide who may have access to
their TMK. However, no description is provided of what would qualify as sufficient or insufficient exploitation. It may then be presumed that an assessment of the prevailing circumstances in each case would have to be undertaken to make this determination. Perhaps, the national authority or a court of competent jurisdiction may be called upon to make such an assessment. It is submitted that although compulsory licensing reduces the extent to which traditional communities may autonomously regulate the use of their TK, this is with good reason particularly in the context of TMK as a greater purpose is served.

v. **Equitable Benefit Sharing**: The sharing of benefits derived from commercial or industrial use of TK is to be determined by mutual agreement between the parties according to section 9 of the Swakopmund Protocol\(^{145}\). The benefit sharing may extend to non-monetary rewards\(^{146}\). The provision for sharing of non-monetary benefits is a practical one as the needs of traditional communities may vary. Particularly in the context of TMK, benefits derived may include the development of new drugs or treatments. The Swakopmund Protocol leaves much room for discussion between traditional communities and access seekers. This “flexibility” may be viewed from two perspectives. On one hand, it may be advantageous in terms of freedom of contract and that non-rigid rules of benefit sharing accommodate various kinds of TK being incorporated into agreements. On the other hand, in the interests of local communities it may have been desirable to include minimum equitable benefit sharing standards.

### 4.3Remarks

The Swakopmund Protocol is an instrument which is the result of 10 years of research and consultative work with traditional communities and other stakeholders\(^ {147}\). It is indeed a significant developmental step in the protection of TK in general including TMK and embodies the idea of a sui generis protection system for TK. The Protocol takes cognizance of the unique nature of TK and has factored this uniqueness into the style of drafting of sections and implementation. Although the Protocol is not without fault as pointed out in this chapter, it is a commendable development in the African context by AR IPO.

---


\(^{146}\) *Ibid* Section 9.3 of the Swakopmund Protocol.

\(^{147}\) (Accessed 20 March 2017) [http://www.aripo.org/services/traditional-knowledge](http://www.aripo.org/services/traditional-knowledge)
Chapter 5 – A Case Study: Zambia

This chapter seeks to examine Zambia in the context of its approach to the protection of TMK as an ARIPO member state and to explore possibilities of improvement for the protection of TMK.

5.1 Legal Status of TMK in Zambia

The Zambian legal system can be traced back to its colonial history. Zambia, as a British colony inherited many laws which were existing in England by virtue of the Foreign Jurisdiction Act of 1843. The Crown permitted the people of Northern Rhodesia as Zambia was then known to continue living by their traditional rules as far as this did not conflict with laws passed by the Crown applicable in the territory.\(^\text{148}\) Following independence, Zambia continued in this vein and adopted a more formal dual legal system. The dual legal system entails that inherited Zambian English Law and Zambian Customary law are applied simultaneously.\(^\text{149}\) In the context of TMK, the dual legal system is a positive thing because the express recognition granted to customary demonstrates a level of respect for customary law as a legitimate system and by extension customary medical practices.

Zambia is a dualist state hence in order for a foreign instrument of law to have a binding and justiciable effect in the territory of Zambia, following ratification, such an instrument must be domesticated.\(^\text{150}\) Domestication entails that a domestic law, either by statute or decree must be enacted in order to give effect to the instrument. As a member of ARIPO, Zambia became the seventh state to ratify the Swakopmund Protocol on 28th August 2015\(^\text{151}\) and in June 2016 through enactment of the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act (PTK Act) domesticated the Swakopmund Protocol. Thus, Zambia has given full legislative effect to this protocol and the provisions contained therein are fully justiciable in the territory.

\(^{149}\) Seidman, 1973, p.40.
\(^{150}\) Starke, 1986, p. 72.
Zambia is a party to the CBD and ratified the instrument in 1993. Since ratification, the National Biodiversity Strategy and Action Plan has been the main policy used to implement the CBD\textsuperscript{152}.

The administration of the CBD is generally cared for by the ministry of Tourism, Environment and Natural Resources through the Forestry Department and the Environmental Council of Zambia\textsuperscript{153}. Until 2007 the focus of the implementation was largely directed towards the conservation of biodiversity with little attention being paid to the intellectual property aspect of TK and the rights which accrue therewith\textsuperscript{154}. Zambia has undertaken domestication of the CBD in stages and has chosen to implement it in different statues. This means incorporation of principles from the CBD into different pieces of domestic legislation such as the Environmental Protection and Pollution Control Act\textsuperscript{155} and the Environmental Management Act\textsuperscript{156}.

The government of Zambia recognizes traditional medical practice. In 2015, efforts were underway by the government to draft an official Traditional Health Practitioners’ Bill designed to regulate the practice of traditional medicine in Zambia. As of March 2017, the Zambian Ministry of Health stated that some progress has been made towards the completion of the Bill however, the Bill is still being worked on.\textsuperscript{157} Meanwhile the formulation of organisations such as the Traditional Healers Association of Zambia (THAZ) which presently has over 35,000 members\textsuperscript{158}, and the Zambia Association of Ng’angas\textsuperscript{159} which has over 10,000 members actively harvesting and using a range of plant related medical remedies is evidence that the use of TMK in Zambia is ongoing and recognized. Additionally, an estimated over 500,000 healers remain unregistered or are non-member practitioners.\textsuperscript{160}

\textsuperscript{152} The current policy is the 2015-2025 policy – See \url{http://www.biodiv.be/zambia/implementation/legislation} (Accessed 01 June 2017).
\textsuperscript{154} WIPO (IGC), 2010.
\textsuperscript{155} Act No. 12 of 1990 Chapter 204 of the Laws of the Republic of Zambia.
\textsuperscript{156} Act No. 12 of 2011 Chapter 199 of the Laws of The Republic of Zambia.
\textsuperscript{157} (Accessed 06 June 2017) \url{https://www.dailynation.news/2017/.../govt-to-table-bill-to-control-traditional-healers}
\textsuperscript{158} The Association was founded in 1978 and is responsible for the review and registration of traditional practitioners for licensing. Although there are no official regulatory measures for recognizing the qualifications of traditional practitioners, necessary steps are being taken by the Government of Zambia towards formulating such a system.
\textsuperscript{159} The word “Ng’angas means “traditional doctor” in the local cibemba language.
\textsuperscript{160} (Accessed 06 June 2017) \url{http://www.scidev.net/global/indigenous/news/zambias-traditional-healers-seek-integration.html}
5.2 Social Status of TMK in Zambia

Over 75% of the population in Zambia benefit from TMK. The country is rich in flora which has medicinal properties as it boasts over 4600 flowering plant species, 211 of which are native to Zambia. Additionally, Zambia has a significant number of traditional healers or members of traditional communities who practice traditional medicine based on TMK. The large-scale use of TMK treatments in Zambia is attributable to the strong cultural ties in traditional Zambian communities which are carried on even when members of various tribe assimilate into “modern or mainstream society”. Higher levels of education, exposure to technology and even access to western medicines do not necessarily result in a rejection of traditional medicine usage by Zambians hence the practice remains popular. Additionally, the cost of allopathic medicine is much higher than the cost of traditional medical treatment. It is estimated that allopathic medical treatment can be 5 times more expensive than traditional treatment. This factor is significant particularly because 64% of the population live on less than $1 per day. This economic situation also places traditional medicine as a more viable option financially.

5.3 Use of TMK in Zambia

There over 70 different tribes in Zambia hence the country possesses a range of TMK. For example, the Ila people, located in the western Lusaka area of Zambia use natural plants and trees for medicinal purposes. The Mukundu tree as it is known in the local language or the Acacia Nigrescens tree is an age old medicinal plant for the Ila. The bark of the tree is extracted and then decocted; the resulting lotion from the process is used for the treatment of sore gums.

---

167 The Ila are also referred to as the Baila, Sukulumbe or Shukulumba.
168 Mwanabayeke, 2013, p. 20.
However, holders of TMK have in the past been reluctant to share their knowledge for fear of unpopularity and for fear that their knowledge might be commercially exploited unfairly.\(^{169}\) The Zambian government has since taken initiatives to exploit the potential of TMK and treatments based on TMK by establishing the Zambia Institute of Natural Research in 2004 whose mandate is to integrate the strength of conventional medicine with that of traditional medicine.\(^{170}\) In 2005, for example, the Zambian Ministry of Health commenced clinical trials on three species of traditional medicine for treatment on 25 HIV positive patients. This was done in collaboration with the National Aids Council and a selected group of traditional healers who formulated the traditional herbal treatments for testing.\(^{171}\) Experiments conducted thus far have not been conclusive but further analysis and testing continues to be in progress.\(^{172}\) It is clear that there have been some attempts to derive benefits from TMK however, the full potential of TMK remains untapped in Zambia.\(^{173}\)

Therefore, the need for a clearly regulated protection mechanism for TMK is a pressing matter and the introduction of the PTK Act provides a positive response to this need.

### 5.4 The PTK Act

The PTK Act contains provisions akin to those found in the Swakopmund Protocol in the context of TK. Commentary will be given on various aspects of the PTK Act. It should be noted however that owing to the similarity and at times identical nature of sections contained in the Act with those contained in the Swakopmund Protocol, reference will be made to the same reasoning or argumentation furnished in Chapter 4 regarding the Swakopmund Protocol.

#### 5.4.1 General Observations

##### 5.4.1.1 Detailed Definitions

The Act contains detailed definitions of numerous words and phrases which are used in it. For example, the term “traditional community” is defined as “a human population living in a distinct geographical area in Zambia which is the creator or recognised, according to customary laws and

---


170 (Accessed 05 June 2017) [http://chappsy12.magix.net/index.htm](http://chappsy12.magix.net/index.htm) - Zambia Institute of Natural Research


48
practices, as the creator and custodian of a traditional knowledge, genetic resource or expression of folklore and the words “community” and “local community” shall be construed accordingly”. This definition is detailed and clearly understandable. It complements the local nature of the Act in that it makes particular reference to Zambia. The attempt made by the Act to provide these extensive definitions is commendable for purposes of understanding the application of the law. However, overly detailed definition may on some occasions serve only to limit the application of the law and create a narrower scope than was initially envisioned. In my view however, the effect of the patterns of definition adopted in the PTK Act is to clarify the terms and to broaden applicability of the Act.

5.4.1.2 Exceptions

Section 3(3) of the PTK Act states that “Despite the other provisions of this Act, the use of traditional knowledge, genetic resources or expressions of folklore for educational, research and experimental purposes shall be exempt from the provisions of this Act.” This type of exception is not uncommon in mainstream intellectual property law regimes and in some areas, steps have been taken to strengthen these exceptions with particular emphasis on the educational and research exception. The exception in the PTK Act is broad and presents a twofold effect in the context of TMK. Firstly, it is a positive thing for research to be conducted in order to advance the use of TMK and discover better ways of harnessing and isolating various medicinal properties of traditional plants used. Additionally, educating people on the availability of TMK is a vital part of moving towards a more accepted and widespread beneficial use of TMK. The second effect however raises potential cause for concern in that persons wishing to become commercial users or users in other contexts outside traditional use may come under the guise of research, experimentation or educational use in order to fall under the section 3 exception. This means that although well intentioned, the section may become a hiding place for unscrupulous individuals.

It is therefore necessary to implement precautions to prevent the abuse of this section. The use of the TMK in research and education should entail that attempts to put any positive results or findings of such research to commercial use would require permission to be obtained from traditional communities and the TMK would then become subject to being put to commercial use only in accordance with the requirements as set out in the PTK Act.

5.4.1.3 Administration

The Act identifies “The Agency” in section 5(1) as being responsible for the administration of the Act. In Section 2 this Agency is identified as the Patents and Companies Registration Agency (PACRA). The selection of PACRA as the administrative overseer of the Act is an interesting choice because it creates the impression of aligning the protection of TK with the patent system. It is submitted that the ideal scenario would have been to form a unique body designed to cater for the needs peculiar to TK systems manned with experts in the field of various aspects of TK including TMK and with representatives from various traditional communities serving in different capacities. However, it is acknowledged that organising the creation of such a body would require considerable time and resources which may not be at the disposal of the Zambian government presently. However, because the Act is barely a year old, it remains to be seen whether PACRA will be able to efficiently carry out this designated role of administrator.

Section 6 of the PTK Act creates the position of Registrar and delegates various responsibilities to the Registrar including the raising of awareness of TK protection. The Registrar also bears the responsibility of acting as advisor to traditional communities on the enforcement of their rights175. To date there are no records of the registrar representing a traditional community in an advisory capacity176. Due to the youth of the Act, it is possible that there remains a low level of awareness of its availability and applicability to traditional communities hence it is not being utilised to maximum potential. According to interviews held with PACRA177 no enquiries have been made and presently the focus is on holding stakeholder consultative meetings with the Minister of lands and the Zambia Environmental Management Agency relating to the establishment of a task force for the administration of the PTK Act.

5.4.1.4 Dispute Resolution

Section 56 enables the Registrar to hear disputes under the PTK Act. Disputes may involve registration issues or authorized licensing agreements. It must be noted that these documents which may be the subject of disputes are issued or authorized by the registrar himself hence the element of bias or lack of impartiality is a significant possibility. In effect, the Act in this regard vests administrative and judicial powers in the same individual. It is submitted that this situation

175 Section 6(b) of the PTK Act.
176 Interview conducted on 15 May 2017 with of PACRA. See Annexure 1.
177 Supra
is undesirable due to the theory of separation of powers\textsuperscript{178} and violates the natural justice principle of nemo \textit{iudex in causa sua} to which Zambia subscribes\textsuperscript{179}. In this vein it is submitted that a separate body independent of the registrar must be mandated with hearing disputes. This body may sit in a quasi judicial capacity and render judgments accordingly. Of course such judgments must be appealable to the Zambian High Court however, it should be made compulsory for a dispute to first be heard and attempted to be resolved by the body. Being a quasi judicial body, various remedies may be available including compensatory and restorative remedies. A decentralization of power increases the chances for dispute resolution to be conducted more fairly and objectively without the interference which is caused when one hearing the dispute or judging a matter is an interested party.

Section 18(9) provides for dispute resolution over holders of TK to be settled in accordance with “the customary laws and practices of the traditional communities involved.” Although this demonstrates respect for community law and traditions of local communities, it is submitted that this method of dispute resolution may present practical challenges. As noted in earlier, Zambia has over 70 tribes each of which possess unique customary laws. Although the customary laws and practices of dispute resolution are not entirely different and unfamiliar, there exist certain differences from tribe to tribe. The question then becomes, which customary law must be applicable in the resolution of the dispute? Which criteria should be employed to select which customary law will prevail? These questions are not easily answered. A suggested method could be to attempt to find common ground between tribes however, again this may not always be possible. Application of a third neutral customary law to settle the issue may be an option however the same questions arise regarding the criteria for selection of this third “neutral customary law”.

5.4.2 Other Observations

5.4.2.1 Automatic Protection

Section 15 of the PTK Act regarding automatic protection is akin to Section 5 of the Swakopmund Protocol. Therefore, as mentioned earlier TK holders are not saddled with executing any

\textsuperscript{178} (Accessed 13 May 2017) \url{https://zambiadailynation.com/2013/09/23/separation-of-powers/}. Although separation of powers is usually referred to in the context of arms of government, the underlying principles which underscore the concept can be applicable here. The idea is to avoid tyranny and promote checks and balances by vesting power in various persons or bodies.

\textsuperscript{179} The Latin phrase \textit{nemo iudex in causa su\texta}\ means “no one should be a judge in his own matter”. This entails that the decision maker in a dispute should be free from bias. It is also referred to as the rule against bias. See: Sinkala, 2008, p.8.
formalities to get the benefits of protection. Section 11 however, introduces a TK register. Registration is not mandatory and does not amount to disclosure of TK where the knowledge is kept away from the public. TMK is inherently an oral system and is on little occasion recorded thus although the registration may not include particulars of exactly what the TMK is and does not amount to disclosure where the knowledge is kept away from the public, the register may at least prove the existence of the knowledge which serves as a starting point for the verification of it which could ultimately lead to positive utilization and prevent it fizzling out. This registration may also serve as a defensive protection measure for TMK.

5.4.2.2 Benefit Sharing

Section 16(2) of the PTK Act demands that “a benefit derived by a traditional community shall be put to the common benefit of the traditional community.” This reinforces the sense of community associated with TK and as it is developed cumulatively and communally the benefits must be distributed accordingly. The issue of benefit sharing is presented in section 43 as including *inter alia*, upfront payments, milestone payments, joint intellectual property ownership, participation of Zambian nationals in development and research based on the TK, employment opportunities, provision of equipment and infrastructure, access to products and technologies derived from the TK. The detail in this section is commendable and in the context of TMK will prove beneficial to Zambian holders of TMK as it presents the opportunity for communities to continue benefit from medicines derived, and other opportunities generated by the use of their knowledge.

5.4.2.3 Duration of Protection

The duration of protection of TK in Section 24 of the Act harmonizes with the standard set by the Swakopmund Protocol in granting protection in perpetuity\(^{180}\). This is beneficial to TMK holders and the communal and cumulative nature of TMK.

5.4.2.4 Continued Use

An essential feature of the Protocol which has been maintained in Section 22 of the Act is the permission of the use of TK in the traditional context remaining unaffected by the existence of the protection offered. This is key to the integrity of the TMK system and prevents interference with the continued existence and application of medical knowledge and treatment regimes in the traditional context.

\(^{180}\) Protection is limited to 25 years where the TK is owned by an individual.
5.4.2.5 Moral Rights

Section 21 of the PTK Act addresses the moral rights aspect of TK protection by creating the obligation to recognize or acknowledge the holders of TK. This is vital because TMK often forms the basis of further development in medical inventions or plays a contributory role in the development of valuable pharmaceutical products for which no acknowledgement is given to traditional communities.

5.5 Remarks

The introduction of the Act is undoubtedly a positive and progressive development in the protection of TK in Zambia. The Act encourages traditional communities to derive benefits from the TK which they possess and creates an increased opportunity for economic development to stem from the sphere of TK in the country. The existence of a regulatory framework and legal protective mechanism for the use of and dissemination of TMK by users may boost investors not to shy away from taking the opportunity to commercialize TMK without fear of legal repercussions provided all the relevant procedure in accordance with the act is followed meticulously.

From the perspective of TMK holders, the coming into force of the Act will encourage them to come forward with their knowledge and enable to benefits. Additionally, the perception that TMK is for those who lag behind with development will be changed in that TMK is being incorporated into present and trending laws and legal systems.
Chapter 6 – Conclusion

The value of TMK at community level and internationally is indisputable as has been shown in this piece of writing. Chapters one and two outlined the importance of TK and the need to award TMK protection as a component of TK. The numerous threats posed to TMK, the need to protect its potential commercial or economic value and the need to guard against misappropriation all form part of the rationale for its protection.

The following matter to be addressed was whether the patent system was the most suitable approach to adopt to the protection of TMK. Chapter three contained an analysis of the interaction between TMK and the patent system. It was revealed that the two systems are inherently antagonistic and divergent at many points. The underlying principles underpinning each system differ in some respects leading to potential hurdles for TMK obtaining protection within the patents regime.

An analysis was presented from the African perspective in the context of the Harare Protocol. The conclusion drawn from an examination of the patentability requirements was that the ability of TMK to fulfill patentability requirements owing to its nature was questionable. The most contentious aspects were identified as the novelty aspect and the inventive step requirements which present a challenge for TMK to meet as explained in chapter 3.

The typical protection mechanisms for TMK categorized as defensive and positive protection were explored in chapter 3. The limitations and merits of both defensive and positive protection were discussed. Additionally, two further protective mechanisms being the human rights system and sui generis protection though forming a subset of positive protection were considered independently. In reality though, it is submitted that the distinction between positive protection and defensive protection may merely be academic because in some instances, positive protection may give rise to defensive effects and vice versa.

In chapter 4, The CBD was isolated as an international instrument addressing the protection of TMK with particular emphasis on Article 8(j). A critical analysis was undertaken of the strengths and weaknesses of the provision and the conclusion derived is that the article is well intentioned and potentially helpful, however fails dismally with regard to choice of words and the implications thereof as well as a lack of enforceability mechanisms of the principles contained in the Article.
Special attention was given to the Swakopmund Protocol in the form of a detailed scrutinization of selected aspects. Overall, the Swakopmund Protocol as is the case with the CBD is well intentioned and certainly contains some positive aspects. It is tailored to the peculiar needs of TK and in fact comprises a sui generis system which admirably sets out the rights and responsibilities of TK holders and the procedures to be followed by those wishing to access the knowledge in question. The Swakopmund Protocol appears accommodative of the sovereignty of states to set additional requirements or standards in the protection of TMK and functions as a minimum standard of protection for member states. Although not without flaws, the Swakopmund Protocol is clearly alive to the special needs of TMK and is a commendable advancement for ARlPO member states in the avenue of protection of TK; a true testament to the workability of regional cooperation in the protection of TK.

In chapter 5, Zambia was isolated as a case study being a state which has ratified and domesticated the Swakopmund Protocol and being rich in TMK. It was confirmed that Zambia is actively involved in the use of TMK but is underutilizing the potential commercial value of TMK. This is largely due to the perception of TMK by holders and other community members and an ignorance of the potential value held by TMK. It must be said however that Zambia is one of the few African states which has enacted domestic legislation (in line with the Swakopmund Protocol) to actively protect TK which includes TMK in the Republic. A detailed study of the PTK Act was undertaken by the author and an analysis of selected sections supplemented with information obtained from PACRA. This study led to the conclusion that theoretically the PTK Act promises great protection for TK and appears to be advantageous for various stakeholders in numerous respects. However, no tangible progress has been seen in TMK protection resulting from the Act. This is attributable to the fact that the Act is still in its infant stages having come into force in June 2016. The Zambian government is therefore still working to bring into effect statutory instruments which will effectively “breathe life into the Act” and to organize task forces which will be involved on the ground in the implementation of the Act. In my view, it is vital for the Zambian government through PACRA and other bodies which they may deem appropriate to engage in campaigns among traditional communities in order to create awareness of the existence of the PTK Act and explain its operation. There is a need to empower traditional communities and legitimize TMK by according necessary recognition to traditional healers and completing the proposed Traditional Health Practitioners Bill. Steps must be taken to integrate TMK into mainstream medicine in order to destigmatize TMK and create a mutually beneficial information exchange between traditional systems and mainstream medicine.
The true potential of the PTK Act to bring about significant change as a suis generis system in the protection of TMK in Zambia remains to be seen.

The protection of TMK is not only necessary but is fundamental in order to extend the benefits of TMK to the holders themselves and the wider community. In my view, the patent system is by no means the best suited protective mechanism for TMK. This is largely because the patent system utterly fails to take into account special characteristics of TMK including communal ownership, development over a long period of time and community usage. Traditional medical remedies have been in use for generations and may thus fail to meet the novelty requirement. This fact is not surprising because the patent system was not originally intended to extend protection to the sphere of TMK and was developed in an entirely different context.

I opine that in order to offer the best possible protection to TMK, a multidisciplinary approach is required. The modes of protection discussed in this thesis including documentation, disclosure of origin (defensive protection), suis generis systems, utilization of the human rights systems, trade practices and contracts among others are not mutually exclusive. Thus, they can be applied simultaneously to offer protection for TMK from various angles.

This multidisciplinary approach will however require practical steps to be taken by both traditional communities which hold the rights and various stakeholders including governments. Traditional communities need to be educated on the availability of protection for the TMK they possess and their right to protect and lawfully exploit their TMK. The meaning of benefit sharing agreements and the approach to be taken to mutually benefit parties must also be explained to traditional communities at community meetings or to appointed representatives of the communities. It is suggested that neutral third parties may be appointed by administrative bodies responsible for the implementation and administration of domestic Acts designed to protect TMK. The distribution of benefits too must be transparent and apparent to community members in order to encourage them to come forward with the TMK they possess to achieve the greater good and wider benefits.

The protection of TMK by a global suis generis system is fundamental to overcoming the problem of protection limited by national boundaries. The formulation of an international instrument, appropriately designed under the umbrella of WIPO would be a positive development in the provision of generally uniform protection for TK at a minimum. It must be noted that discussions have been ongoing to develop such an instrument under the guidance or as an initiative of the IGC however no concrete instrument has been developed today and this remains a pertinent
issue. Consultative discussions need to be engaged in more aggressively to ensure results are derived and action is taken.

In conclusion, Africa is rich in biodiversity and knowledge on medicinal use of plants. This valuable information held by traditional African communities must be preserved and maintain its integrity. The best protection for TMK does not lie within the patent system. Forcing protection to be found in the patent system would be tantamount to squeezing TMK into an ill-fitting category of protection, rather the best protection option lies in suis generis systems as demonstrated by the Swakopmund Protocol. Member states need to take steps to ratify and domesticate this protocol as exemplified by Zambia and begin the journey to enable traditional communities and by extension their economies to reap the benefits of lawful exploitation of their TMK. Additionally, suis generis systems need to operate in conjunction with defensive protection measures and other positive protection measures in order to achieve maximum efficiency of protection.
Bibliography

Legislation

International Legislation/Conventions/Instruments
Convention Biological Diversity 1992

The Paris Convention for the Protection of Industrial Property 1883

The Universal Declaration of Human Rights Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948

Regional Legislation/Instruments
The Harare Protocol on Patents and Industrial Designs within the Framework of ARIPO 1982

The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore 2010

The African Charter on Human and People’s Rights 1986

National Legislation
Zambia
The Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act No. 16 of 2016 Chapter 451

Environmental Protection and Pollution Control Act No. 12 of 1990 Chapter 204

Environmental Management Act No. 12 of 2011 Chapter 199

Kenya
Industrial Property Act of 2001 Chapter 509

Sweden
Swedish Patents Decree (2016:580)

Case Law
Tumeric Case :USPTO Reexam. No. 90/004,433, Oct. 28, 1996 for no. 5,401,504
Doctrine

Books


Carolan M., *Decentering Biotechnology; Assemblages Built and Assemblages Masked*, Routledge (2016)


**Journal Articles**


**Other Sources**

**Online Resources**


(Accessed 20 March 2017) http://www.aripo.org/services/traditional-knowledge


Documents of Intergovernmental Organisations

WIPO

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Second Session, Report, adopted by the Committee, WIPO document WIPO/GRTKF/IC/2/16, of December 14, 2001, at paragraph 17


Intergovernmental Committee On Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore Sixteenth Session Geneva, May 3 to 7, 2010

WHO


Other Documents/Reports
Abott R., WIPO Documenting Traditional Medical Knowledge (March 2014)


Mugabe J., “Intellectual Property Protection And Traditional Knowledge; An Exploration in International Policy”, African Center for Technology Studies 1 at pp. 1 (1999)

Mwanabayek B., Ethnic Construction In Central Province Of Zambia: A Case Study Of The Kaonde -Ila People Of Mumbwa District p. 20 -27 (2013)


Permanent Forum on Indigenous Issues Thirteenth Session New York, 12-23 May 2014 Item 9 of the provisional agenda 1: A study to examine challenges in the African region to Protecting Traditional Knowledge, Genetic Resources and Folklore Note by the secretariat


The Rules of Natural Justice Within the Zambian Legal System" by Charles T. Sinkala Feb 2008, University of Zambia
Annexure 1

INTERVIEW HELD WITH J.CHILAMBWE OF THE PATENTS AND COMPANIES REGISTRATION AUTHORITY OF ZAMBIA

Interviewer: Ruth M. Sinkala (RMS)

Interviewee: Justine Chilambwe (JC)

RMS: The enactment of PTK Act is a new and commendable development in Zambia. Kindly answer the following questions I have regarding the Act.

JC: I'll be happy to

RMS: How many TMK holders have registered under the Act so far?

JC: So far, we have had no registration for TMK or any other kind of TK. We as PACRA are still working on putting in place necessary regulations to enable registration to begin.

RMS: How accessible will the register be and what is the basis of fee charging to inspect the register?

JC: We plan for the register to be openly accessible during certain hours but inspection fees are for administrative reasons and the actual price to be charged as a fee is yet to be determined.

RMS: Who is the registrar presently?

JC: Anthony Bwembya

RMS: Has he played any advisory role to traditional communities as envisioned in the Act since its enactment?

JC: He has not yet done so and we have had no such enquiries. At the moment, the focus is on holding stakeholder consultative meetings with the Minister of Lands and ZEMA relating to genetic resources and TK with the view to establishing a task force.

RMS: How do you intend to deal with the issue of possible conflicting customary laws per section 18(9) of the PTK?

1 It should be noted that this is a summarized transcript and parts of the interview which in the view of the author were not pertinent to the outcome have been omitted.
**JC:** We need to establish regulations to address those potential problems after holding consultative meetings.

RMS: How do you intend to address the possible challenges which may be brought about from the section 3(3) exception in the Act?

**JC:** Regulations need to be put in place to ensure this provision is not exploited.

RMS: Final Remarks?

**JC:** The PTK Act is still in its infant stages and work is underway to enact relevant statutory instruments for the Act to begin working on a practical level. Many of these issues will only be addressed once that has been done.

RMS: Thank you for your time.
INTERVIEW CONDUCTED REGARDING PROTECTION OF TRADITIONAL KNOWLEDGE, GENETIC RESOURCES AND EXPRESSIONS OF FOLKLORE IN THE REPUBLIC OF ZAMBIA

Interviewer: Ruth M. Sinkala
Interviewee: Mr. Justine T Tambatamba Chilambwe
Capacity: Examiner
Date of Interview: 15 May 2017
Time of Interview: 09:08hrs

I hereby certify that a telephone interview was conducted by Mrs. Ruth M. Sinkala, a student at Uppsala University in Sweden on the above date regarding the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act No.16 of 2016 of the Republic of Zambia. This was done in pursuance of research being conducted in the field of the Protection of Traditional Knowledge in Zambia.

Mr. Chilambwe
E-mail: j.chilambwe@pacra.org.zm
Telephone: +260211255151
Mobile: +260955796838, +260966796838, +260977796838
Patent And Company Registration Agency