

BIOPIRACY AND THE CASE FOR TRADITIONAL MEDICINE IN KENYA

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DECLARATION

I, RHODAH NOREEN KWAMOKA NYAMONGO, do hereby declare that this research is my original work and that to the best of my knowledge and belief, it has not been previously, in its entirety or in part, been submitted to any other university for a degree or diploma. Other works cited or referred to are accordingly acknowledged.

Signed:

Date:

This dissertation has been submitted for examination with my approval as University Supervisor.

Signed:.....

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ABSTRACT

Traditional medicine as a form of traditional knowledge has for the longest time been inadequately provided for within the legislative framework both locally and internationally. In spite of being in existence for a long time and the awareness of its reliability, it has been poorly protected and the consequence has been biopiracy, that is, unfair misappropriation and exploitation. Only recently has the populace and government in developing countries recognised the necessity of protecting it and ensuring that the rights members of the indigenous and local community who discovered the medicinal knowledge are recognised, preserved and protected.

The study examined the current legislative and regulatory framework globally and in Kenya and came up with recommendations which Kenya can implement in order to prevent biopiracy and create systems through which the holders of traditional medicine can benefit from them. The study was conducted through comparative analysis of the approaches taken by Thailand, India, South Africa and Portugal as opposed to Kenya.

It has found that the newly enacted Statute and international intellectual property laws have loopholes that greatly foster biopiracy. It has also found that the protection of traditional medicine in Kenya will be greatly promoted through the establishment of an independent institution whose members are well versed or experienced in the area of traditional knowledge, particularly the medicinal practices. The study proposes that the Digital Repository to be established be made available and accessible globally to institutions that deal with the registration of intellectual property rights in order to prevent biopiracy not only locally but internationally.

LIST OF ABBREVIATIONS

ARIPO	African Regional Intellectual Property Organisation
CBD	Convention on Biological Diversity
CSIR	Council for Scientific and Industrial Research
GRs	Genetic Resources
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual Property
IPRs	Intellectual Property Rights
KECOBO	Kenya Copyright Board
NBA	National Biodiversity Authority
NIKSO	National Indigenous Knowledge Systems Office
RRGV	Register of Plant Genetic Resources
TCEs	Traditional Cultural Expressions
TK	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library
TKRC	Traditional Knowledge Resource Classification
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
UDHR	Universal Declaration of Human Rights
UNEP	United Nations Environmental Programme

CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Undoubtedly, the use of traditional medicine has for a long time been seen as inferior or suspect. This attitude can be traced back to the colonial era when traditional African practices and customs including the usage of traditional medicine and reliance on traditional healers was deemed repulsive by the colonialists because it was sometimes wrongly associated with witchcraft.

Moving forward, the use of traditional medicine is widely embraced in numerous countries within Asia, Africa and Latin America. According to the World Health Organisation (WHO), approximately eighty percent (80%) of Africa's population depends on traditional medicine for primary healthcare.¹ This can be attributed to the fact that they are more accessible especially to local communities in rural areas. Furthermore, they are deemed less costly, more effective and less likely to cause undesirable side effects due to their 'natural' characteristic when compared to their pharmaceutical counterparts.

Traditional medicine is not only used for the treatment of human beings but is also used by majority of livestock keepers in the rural areas in the treatment of their livestock.² Traditional medicine practitioners within a community are very vital especially when looking at the current ratio of doctors to patients which is a startling one doctor to 17, 000 of the population³ as opposed to the recommended WHO ratio of one doctor to 1,000 of the population.⁴

The protection of traditional medicine has been an issue under debate in local, regional and international forums, the outcomes of which are national policies, international Conventions and recently a Kenyan law. On 31 August 2016, President Uhuru Kenyatta assented to the Protection of Traditional Knowledge and Cultural Expressions Bill. It has been in force since 21 September 2016. This has brought to life Article 11(3), Article 40 and Article 69(1) (c) of the Constitution of Kenya 2010 which obligates the State to protect the indigenous knowledge

¹ <<http://www.who.int/mediacentre/factsheets/2003/fs134/en/>>on 12 January 2017.

² Para. 4.2.1, *National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions*, Republic of Kenya, July 2009.

³ Okoth D, 'Why doctors' flight is a growing concern in the ailing healthcare system' Standard Digital, 31 May 2013 - <<https://www.standardmedia.co.ke/article/2000084831/why-doctors-flight-is-a-growing-concern-in-the-ailing-healthcare-system>>on 13 January 2017.

⁴ 'Global health observatory data repository', WHO, - <<http://apps.who.int/gho/data/node.main.A1444> >on 13 January 2017.

and property of communities. Only time will tell whether this law will be effective. Prior to this, there was no national law which outlined how to effectively protect these rights from misappropriation and further remunerate the people responsible for their origin or creation.

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), a major source of reference in Intellectual Property (IP) -related matters globally, is still silent on the matter of TK and TCEs. It however permits the exclusion of plants and animals (other than micro-organisms) and biological processes for the production of plants or animals other than non-biological and micro-biological processes from patentability by the member states.⁵ The Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore is a regional effort that provides extensive guidance on what constitutes these IPRs and means of their protection.

Some of the salient features of the Act are: the extensive definitions; the delineation of roles and responsibilities of the national and county governments; requirement for the establishment and maintenance of registers; emphasis on the right to protection and exclusivity of rights holders as well as sanctions and remedies. These shall be extensively discussed and critiqued in Chapter 3. The Act borrows heavily from the Swakopmund Protocol.

The Protection of Traditional Knowledge and Cultural Expressions Act defines traditional knowledge as:

“knowledge which originates from an individual, local or traditional community and is the result of intellectual activity and insight within a traditional context, including know-how, skills, innovations, practices and learning, embodied in the traditional lifestyle of a community; or contained in the codified knowledge systems passed on from one generation to another including agricultural, environmental or medical knowledge, knowledge associated with genetic resources or other components of biological diversity, and know-how of traditional architecture, construction technologies, designs, marks and indications.”⁶

Traditional medicine is the *sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not,*

⁵ Article 27 (3) (b), *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, 15 April 1994, 1869 U.N.T.S. 299.

⁶ Section 2, *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

*used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.*⁷

Traditional medicine is one of the forms of Traditional Knowledge (TK) and can therefore be protected by Intellectual Property. TK and TCEs are symbolic of the communities which they originate from. Presumably, they are intergenerational rights and communally owned- it is hard to trace the original owner of something that was created years and years ago; in an informal setting and in response to a particular problem.

The fact that these IPRs are intergenerational poses a problem in terms of their protection. Perpetual protection would undermine the principles of intellectual property. At the same time, lack of perpetual protection of TK and TCEs would expose them to the risk of dilution once they are availed in the public domain. This would ultimately threaten the culture of various communities thereby undermining the Constitution which gives the State an obligation to promote all forms of national and cultural expression and to promote the IPRs of the people of Kenya.⁸

The following factors have to be regarded while considering the protection and preservation of traditional medicine:⁹

- a) Traditional medicine may be both ancient and contemporary
- b) It may be either written or unwritten
- c) It includes both products or processes
- d) International trade of traditional medical products is gaining momentum thus of increasing significance.

Traditional medicine being a facet of traditional knowledge faces similar challenges when it comes to its protection under the current intellectual property rights' regime. This has resulted in its misappropriation and unlawful exploitation by way of biopiracy to the detriment of the traditional communities. Biopiracy is defined as:

⁷'Traditional Medicine: Definitions', WHO, -
<<http://who.int/medicines/areas/traditional/definitions/en/print.html>> on 4 January 2017.

⁸ Article 11 (2) (a) (c), *Constitution of Kenya*, 2010.

⁹ Wilder R, 'Protection of traditional medicine,' Indian Council for Research on International Economic Relations, Working Paper Number 66, December 2000, 5 <http://icrier.org/pdf/wilder66.PDF> on 2 June 2016.

“the unethical or unlawful appropriation or commercial exploitation of biological materials (such as medicinal plant extracts) that are native to a particular country or territory without providing fair financial compensation to the people or government of that country or territory.”¹⁰

Pharmaceutical companies are alleged to have committed biopiracy. This has been seen in the South African and Madagascar cases below. Indigenous communities especially in developing countries have fallen victim to biopiracy while western individuals and multinationals in the pharmaceutical sector are making a lot of profits from the exploitation of African traditional resources. International patent applications facilitate this to some extent as is visible in the international patent application filed by Bayer Consumer Care Company in 2008 on the use of an extract of *Vernonia* plant from Madagascar in cosmetics, food supplements and pharmaceuticals to improve the skin.¹¹

One of the most celebrated cases to date, is that of the *Hoodia gordonii* plant that has for years been used by the San people of Southern Africa to stave off hunger and thirst. The Council for Scientific and Industrial Research (CSIR), South Africa found that the plant contains a hunger-suppressing chemical component and sold the rights to develop an anti-obesity drug to Pfizer, a pharmaceutical company.¹² This was done without consent of the San people. However this was reversed when the San people launched a claim against CSIR claiming violation of the Convention of Biological Diversity 1992 that requires prior consent of the party providing the resources.¹³ CSIR and South African San Council later signed an access and benefit sharing agreement to recognize and reward the San as holders of traditional knowledge.¹⁴

A recent case, closer home which shows the implications of the absence of legal recognition for indigenous knowledge is the five year-long battle between the Maasai of Tanzania and Thomson’s Safari, a US based Tourist Company. The Maasai disputed the sale and ultimate conversion of their land to a tourist site because this land was the source of their indigenous knowledge because it had different plant species that were used in the formulation of traditional

¹⁰ Merriam Webster Dictionary Online, - <http://www.merriam-webster.com/dictionary/biopiracy> on 11 August 2016.

¹¹ ‘World Intellectual Property Organisation’ <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2008125237> on 2 November 2016.

¹² Ong’wen O, ‘Biopiracy, the intellectual property regime and livelihoods in Africa,’ 10/2010 - <http://base.d-ph.info/fr/fiches/dph/fiche-dph-8699.html> on 2 June 2016.

¹³ Article 15 (6), *Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79.

¹⁴ *Hoodia gordonii*, the San tribe and biopiracy,’ - http://www.rebirth.co.za/hoodia/san_tribe_and_biopiracy.htm on 2 June 2016.

medicine. The land was also used in cultural rituals and ceremonies. Their argument was apparently insufficient because the High Court of Tanzania ruled in favour of Thomson's Safari instead.¹⁵

Bayer, a German pharmaceutical company, is alleged to have manufactured the diabetes drug, Glucobay (acarbose) using bacteria called *Actinoplanes SE 50*, acquired from Lake Ruiru in Central Kenya.¹⁶ To date, no benefits have accrued to Kenya for this discovery. There is no evidence of benefit sharing or compensation of the local communities or Kenya itself. This is inequitable. There are still other instances when Kenya has fallen victim to biopiracy yet no lawsuit has been filed. This can be attributed to the ignorance of many indigenous communities of the rights due to them owing to the exploitation of their cultural property.

Over time there has been a lot of discussion as to whether a sui generis regime would befit the protection of these rights that are seen as 'non-conventional'. This is fuelled by the increasing realisation and recognition of the role played by traditional medicine- not only as a symbol of the indigenous culture of a community but also as a factor that is likely to contribute to the sustainable and economic development of the Kenyan nation if properly protected and used. Furthermore, traditional medicine is essential to the realisation of the constitutional right to the highest standard of health¹⁷ because it is an alternative to 'modern' medicine.

¹⁵ Theuri C, 'Maasai lose 5 year battle to revert land sale and protect their indigenous knowledge' IP Karibu, 24 December 2015- <http://www.ipkaribu.com/single-post/2015/12/24/Maasai-lose-5-Year-Battle-to-Revert-Land-Sale-and-Protect-their-Indigenous-Knowledge> on 11 January 2017.

¹⁶ Kimani D, 'Biopirates: Bayer earns \$379m from diabetes drug,' East African, 13 February 2006- <http://www.cbgnetwork.org/1357.html> on 2 June 2016.

¹⁷Article 43(1), *Constitution of Kenya*, 2010.

1.2 STATEMENT OF PROBLEM

Traditional medicine has been in use and existence since time immemorial. In the past, the need for protection may not have been urgent because the medical knowledge was used within the community and for the benefit of the community. Instances of misappropriation were unforeseeable in the past. Presently the instances of misappropriation and wrongful exploitation of traditional medical knowledge is seen. It is no surprise that some instances of it go unreported.

The indigenous communities are faced with challenges such as lack of recourse for the wrongful exploitation. Some are simply unaware of the value of their knowledge or its importance. Consequently, western communities are credited for these 'discoveries'. At the end of the day, indigenous communities fail to be fairly compensated for the benefits accrued and owed to them. In addition to this their moral rights are infringed on.

Kenya has in place a new statute aimed at preserving among other things, traditional medical knowledge. The Act seems to be unclear on a few matters such as the differentiated roles of KECOBO and the county governments when it comes to dispute resolution. Such ambiguity may inhibit the adequate protection of traditional medicine and pose a problem in the future.

1.3 JUSTIFICATION OF STUDY

Traditional medicine or traditional medical knowledge not only provides a source of health care but is also a source of identity for the community credited for it. It is therefore a source of economic benefit. The protection of traditional medicine is therefore vital in order to foster and facilitate the continuous economic and social development of local and indigenous communities and Kenya as a whole. It is important to curb and prevent further biopiracy which may foster loss of revenue as well as erosion of intellectual property rights.

There is therefore need to analyse the legislative and enforcement framework in order to strengthen the institutions and prevent further biopiracy.

1.4 STATEMENT OF OBJECTIVES

The specific objectives of the study are:

- a) To identify whether the current Act and enforcement mechanisms may be inadequate in the protection of traditional medicine.
- b) To investigate the impact of the inadequate protection on traditional medicine and the right to protection of indigenous knowledge.

- c) To identify means of effectively overcoming biopiracy in Kenya and strengthening the institution of traditional medicine.

1.5 RESEARCH QUESTIONS

This study aims to answer the following questions:

- a) How does the current international and national legislative framework dealing with biopiracy?
- b) Does the controversy that currently exists between the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and the Convention on Biological Diversity (CBD) contribute to the growth of biopiracy?
- c) How do the roles of Kenya Copyright Board (KECOBO) and the county government differ with regard to protection of traditional medicine is?

1.6 RESEARCH DESIGN AND METHODOLOGY

In this study, I intend to critically analyse the current laws and enforcement infrastructure protecting traditional medicine within the Kenyan intellectual property framework to establish their adequacy in the protection of traditional medicine from biopiracy and whether the sanctions and remedies afforded to the indigenous communities are adequate. I also intend to contextualise the problem of biopiracy in the regional and international context. I also intend to carry out a comparative analysis of our laws, infrastructure and enforcement mechanisms with two other countries in order to appreciate how they tackle the issue of biopiracy and how Kenya can learn from them.

This research will also use look at the approach taken by other countries such as India, South Africa, Thailand and Portugal. These countries are known to possess rich traditional medicinal knowledge and biodiversity and have therefore taken steps to remedy the plight of biopiracy. For instance, India is a pioneer in the establishment of a digital database that has indeed strengthened its efforts in the fight against biopiracy.

My research will focus broadly on internet resources. I intend to rely on secondary data which I will obtain from statutes, international instruments, WIPO reports, scholarly articles, journals, online articles and cases relevant to my research. I will rely majorly on sources from online databases such as Jstor, Edinburgh and Wiley Online Library.

1.7 LIMITATIONS

The main focus of this study is to look at biopiracy in Kenya and the problems that it poses to the protection of intellectual property rights in traditional medicine. It will therefore look the laws and infrastructures in place which facilitate this. Owing to the fact that the Act aimed at spearheading the protection of traditional medicine was passed recently I expect to be faced with challenges such as inadequate secondary data and statistics. I further expect to challenges such as time constraints in data collection.

It will also be limited to case studies from member states of the African Regional Intellectual Property Organisation (Kenya is a member state), developing states such as India and developed states such as Thailand which are also affected by misappropriation of their indigenous knowledge by foreign states.

1.8 CHAPTER BREAKDOWN

Chapter two will entail an analysis of the philosophical foundations that underlie the protection of traditional medicine as an intellectual property right and how biopiracy undermines it.

Chapter three will contextualise the issue of biopiracy and analyse the international and national legislative framework put in place to protect traditional medicine in the Kenyan intellectual property framework and prevent biopiracy. It will look in depth at the legislative, regulatory and enforcement mechanisms put in place in Kenya. It will look at the adequacy and sufficiency of the framework.

Chapter four will analyse the limitations faced thus far by the current legal framework and enforcement mechanisms in place. It will also include a comparative analysis of the approaches taken by other states.

Chapter five will seek to provide a summary of the analyses in the preceding chapters and the issues that arose and will suggest and recommend a way forward with regard to the tackling of biopiracy of traditional medicine and the effective compensation of the local and indigenous communities.

CHAPTER TWO: THEORETICAL FRAMEWORK

There are three forms of biopiracy; these are: bioprospecting, discovery of unknown properties in known plants and organisms and finally the exploitation of traditional medicine.¹⁸ Biodiversity prospecting, commonly known as bioprospecting is defined by the CBD Secretariat as the process by which a person carries out investigative research of biodiversity in search for genetic resources or microorganisms in a bid to finally exploit those resources for a profit.¹⁹ This is the least piratical form of biopiracy because at this point actual appropriation has not taken place.

The second form refers to a situation where new or unknown properties are discovered in known plants and organisms.²⁰ Finally, the last form which is the focus of this paper, is the actual exploitation and misappropriation of the indigenous knowledge of a community by foreigners without their permission and due compensation.

Before embarking on an analysis as to whether the current safeguards in place, particularly the newly passed legislation is inadequate in preventing biopiracy and ensuring adequate compensation of the communities, it is important to look at philosophical underpinnings that justify the protection of traditional medicine as an intellectual property rights and further disrepute biopiracy as a practice.

William Fisher defines intellectual property as a *loose cluster of legal doctrines that regulate the uses of different sorts of ideas and expressions thereof*.²¹ It is therefore effected through the various categories of trademark law, copyright law, patent law and trade secret law. Some of the commonly cited theoretical foundations in the field of intellectual property are utilitarian theory and natural rights theory. These two theories will be instrumental in making a case for traditional medicine in this paper.

¹⁸ Garcia J, 'Fighting biopiracy: The legislative protection of traditional knowledge,' 18 *Berkeley La Raza Law Journal*, 2007, 7-8.

¹⁹Slobodian L, Kinna R, Kambu A and Ognibene L, 'Bioprospecting in the global common: Legal issues brief', UNEP - <http://www.unep.org/delc/Portals/119/Biosprecting-Issuepaper.pdf> on 10 January 2017.

²⁰ Garcia J, 'Fighting biopiracy: The legislative protection of traditional knowledge', 8.

²¹ Fisher W, 'Theories of intellectual property', 1- <https://cyber.harvard.edu/people/tfisher/iptheory.pdf> on 17 February 2016.

2.1 NATURAL RIGHTS THEORY

2.1.1 Labour Theory

The Labour Theory is attributed to John Locke who makes a primary assertion that people own themselves.²² Although men as a whole own the earth, every individual man has a property in his own person that no one else has a right to save for himself. When a person takes something from nature or the commons and exerts his labour on it therefore joining or mixing something of his own with nature, he makes such thing- the fruits of his labour, his property.²³ This means that a person owns that which he has transformed from its original natural state to something personal. He alone therefore has a right to the outcome or product to the exclusion of others. God makes the things in nature for the use of man and no one has a basic or natural right to them unless they appropriate them and make them useful.

John Locke proposes that a person who labours upon resources that are held in common has a natural property right to the fruits of his or her efforts and consequently the state has a duty to respect and enforce the resulting natural right.²⁴ Biopiracy in this context endangers the intellectual property of indigenous communities and goes against the natural rights theory. Traditional or local communities have for a long time appropriated these natural resources learning the intricacies surrounding the use of particular plants or herbs for medicinal use so much that this knowledge and skills have been passed down from generation to generation and the community is identified with those practices.

Similarly, protection of traditional knowledge and the cultural expressions is justifiable on the grounds that they are indigenous and attributable to a specific group of persons who have a natural right to them to the exclusion of others unless the latter have sought permission from the holders and have given them compensation in return.

This is further echoed in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) in Article 31 which although not ratified by Kenya can be used as a persuasive reference:

‘Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human

²² Morrissey M, ‘An alternative to intellectual property theories of Locke and utilitarian economics’, Unpublished Master of Arts Thesis, Louisiana State University and Mechanical College, 2012, 3.

²³ Locke J, ‘Property’ in *Second Treatise of Government*, 2005, 11-<http://www.earlymoderntexts.com/assets/pdfs/locke1689a.pdf> on 4 January 2017.

²⁴ Fisher W, ‘Theories of Intellectual Property’.

*and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.*²⁵

The labour rights theory has been criticised as a justification for the protection of intellectual property rights because it suggests that these intellectual property rights are inherent and inalienable yet essentially these rights are subject to the legal and regulatory framework of the State which are further informed by the social, economic and political circumstances of the State.

In Kenya, property rights are not absolute and one can be deprived of their property if necessary for public interest. Most intellectual property rights granted by the government are limited and non-renewable upon expiry. For example industrial property such as patents can only be granted for 20 years from the date of filing of the application²⁶ whereas plant breeders' rights are generally granted for twenty years from the date of the grant.²⁷

2.1.2 Personhood Theory

The Personhood Theory is attributed to writers such as Friedrich Hegel and Margaret Radin. Accordingly, a person requires some control over things in the environment in order to achieve self-fulfilment as an individual and property rights assure a person of this control.²⁸ Radin's perspective of the theory espouses the notion that people possess objects which are so closely tied to themselves that separation from them or their loss would cause the owner so much pain that cannot be relieved by the object's replacement. One of the main objectives for the protection of intellectual property particularly traditional medicine is not necessarily to prevent the sharing of it but to allow the sharing of it subject to the fair compensation of the indigenous communities identified with such knowledge.

Hegel's model is premised on the fact that creators have an inherent right to protect the integrity of their creations as much as they have the right to protect their personalities. Private property rights play the role of ensuring self-fulfilment of the individual.²⁹

²⁵ Article 31(1), *UNDRIP*, 13 September 2007, A/RES/61/295.

²⁶ Section 60, *Industrial Property Act*, Act No. 3 of 2001.

²⁷ Section 19 (1), *Seeds and Plant Varieties Act*, Act No.1 of 1972.

²⁸ Radin M, 'Property and personhood' 34(5) *Stanford Law Review*, May 1982, 957.

²⁹ Fisher W, 'Theories of Intellectual Property', 5.

More emphasis is put on the creator's dignity than the fruit itself as intellectual property rights are intended to prevent the appropriation and modification of the means through which creators have expressed their wills.³⁰ This means that intellectual property rights intermingle with the personality of the creator entitling them to the moral rights at the very least. This is especially true of copyrights where the moral rights of the owner still subsist even after the owner assigns or licenses the economic right to another person.³¹ The law entitles a person to seek remedies where their work is used in a manner that abrogates their moral rights in that, the act is prejudicial to them and likely to distort their reputation in addition to their work.³²

Traditional medicine is symbolic to the communities that hold them as they are a source of their identification and many times are inseparable from the communities responsible for them. The medicinal use of turmeric has been widely associated with India and closer home, the use of the *hoodia gordonii* plant as an appetite suppressant by the San people of the Southern Africa region. The latter has been used by the San community for ages as a means of adapting to the dry environment that they live in as a result of their economic and social means of life.

Indigenous communities that are identified with them should therefore be accorded respect from the public and the requisite amount of money in exchange for sharing their knowledge as opposed to surrendering their moral rights and thereby allowing for their mutilation and misattribution as is the case with biopiracy.

In addition to this, the Universal Declaration of Human Rights (UDHR) recognises that everyone possesses the right to the protection of the moral and material interests that accrue from the scientific, literary or artistic creations.³³ This same provision is further echoed in the International Covenant on Economic, Social and Cultural Rights (ICESCR) which adds that such a right accrues to the author of such creations.³⁴

The Protection of Traditional Knowledge and Cultural Expressions Act provides that owners of these intellectual property rights shall also possess or own the moral rights in them³⁵. They are therefore entitled to the attribution of ownership in their traditional knowledge and cultural expressions³⁶ and this knowledge and cultural expressions should not be treated in such a

³⁰ Fisher W, 'Theories of Intellectual Property' 5.

³¹ Section 32 (1), *Copyright Act*, Act No 12 of 2001.

³² Section 32 (3), *Copyright Act*, Act No. 12 of 2001.

³³ Article 27(2), *UDHR*, 10 December 1948, UNGA A/Res/ 217(III)

³⁴ Article 15(1), *ICESCR*, 16 December 1966, UNTS 993.

³⁵ Section 21(1), *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

³⁶ Section 21 (2) (a), *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

manner that diminishes its value or that dishonours the reputation of the community.³⁷ A community is further entitled to protection against to false claims of authenticity or origin of traditional knowledge and cultural expressions.³⁸

One avid proposer of the personhood theory from Hegel's perspective is of the thought that the government should be more willing to accord legal protection to what he refers to as "highly expressive intellectual activities" such as authoring books than otherwise "less expressive activities" such as genetic research.³⁹

2.2 UTILITARIANISM

According to the utilitarian theory, the achievement of the maximum social net welfare should dictate the allocation of property rights.⁴⁰ In other words, intellectual property rights should be fashioned in a manner that allows the achievement of the best consequences possible in order to promote happiness or pleasure and avoid pain.⁴¹ Traditional medicine is still heavily relied on by many as a primary source of healthcare especially because of its effectiveness;⁴² availability; it is cheaper than the pharmaceutical drugs and does not have significant side effects. Furthermore, traditional medicine is commonly used in pharmaceutical products as their major active ingredient hence the current issue of biopiracy.

Utilitarian theorists advocated for the creation and protection of intellectual property rights in order encourage innovation and promote new technologies necessary for development.⁴³ The granting of these intellectual property rights was however contingent on the imposition of limits such as the duration of exclusive ownership in order to avoid the creation of monopolies.

Based on this theory, sufficient and adequate intellectual property right protection should be accorded to traditional medicine in order to prevent further instances of biopiracy in Kenya. Traditional knowledge as a whole is of great utility not only to the indigenous community it originates from but also the state of Kenya in its entirety. The society relies on the production of this traditional medicine for the improvement of its welfare. The utilitarian theory conceptualises the imposition of limits on intellectual property rights in order to prevent

³⁷ Section 21 (2) (c), *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

³⁸ Section 21 (2) (d), *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

³⁹ Hughes J, 'Philosophy of intellectual property' 77 *Georgetown Law Journal* 287, 1988-
<https://cyber.harvard.edu/IPCoop/88hugh2.html#n167> on 5 January 2017.

⁴⁰ Fisher W, 'Theories of intellectual property' 2.

⁴¹ <https://www.utilitarianism.com/utilitarianism.html> on 5 January 2017.

⁴² 'Herbal remedies do work' BBC News <http://news.bbc.co.uk/2/hi/health/3698348.stm> on 5 January 2017.

⁴³ Menell P, 'Intellectual property: General theories' 1999, 129- <http://levine.sscnet.ucla.edu/archive/ittheory.pdf> on 4 January 2016.

economically inefficient outcomes such as the inability of the creator to recoup the costs of expression following issues such as biopiracy.

The Protection of Traditional Knowledge and Cultural Expressions Act 2016, incorporates the utilitarian theory. For example, the Act limits the duration of protection of traditional knowledge⁴⁴ and cultural expressions⁴⁵ against misappropriation and unlawful exploitation to the time during which it fulfils certain criteria. In the case of traditional knowledge, it is intergenerational in nature; it is characteristic to a particular community and plays a major role in identifying the community culturally.⁴⁶ This clearly follows the objective of the utilitarian theory- seeking to avoid inefficient outcomes such as misappropriation.

⁴⁴ Section 13, *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

⁴⁵ Section 17, *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

⁴⁶ Section 6, *Protection of Traditional Knowledge and Cultural Expressions Act*, No 33 of 2016.

CHAPTER THREE: LEGISLATIVE, REGULATORY AND INSTITUTIONAL FRAMEWORK FOR THE PROTECTION OF TRADITIONAL MEDICINE

The legal and institutional framework has undergone a number of changes since the recognition of biopiracy as an issue that is endemic to the abrogation of cultural and economic rights of indigenous and local communities of Kenya. The first section of this Chapter will give a broad analysis of the legislative and institutional framework in Kenya with regards to traditional medicine and prevention of biopiracy. The second part will look at the legislative and institutional framework at a regional level (Africa) whereas the third will look at the legislative and institutional mechanisms in place internationally.

3.1 DEVELOPMENT OF THE LEGISLATIVE AND INSTITUTIONAL FRAMEWORK IN KENYA

3.1.1 History of Protection of Traditional Medicine in Kenya

While looking at the development of the legislative framework, it is important to take into consideration the legislative history which serves as a foundation for understanding why the protection of traditional medicine is necessary and why biopiracy not only affects the economic rights of the indigenous and local communities but also erodes their cultural heritage. Kenya is made up of over 40 ethnic groups with different languages, cultural beliefs and heritage. Each of these groups is governed by a customary law system that has been in place since time immemorial with rules that are uncodified.

As briefly mentioned in Chapter one, traditional medicine and the use of medicinal plants was greatly demeaned and perceived as primitive from the onset of the colonial era by colonial authorities. The colonial authorities sought to undermine this through criminalising it and attempting to impose their imperialistic beliefs on communities.⁴⁷ The enactment of the Witchcraft Act in 1962 criminalised the use of traditional medicine thus discouraging the traditional practitioners themselves. This Act is still in force to date. The practice of traditional medicine began to resurface again during the late 1970s when it became apparent that it supplements modern health or medical arrangements in a positive way.⁴⁸

⁴⁷ Ongugo P, Mutta D, Pakia M and Munyi P, 'Protecting traditional health knowledge in Kenya: The role of customary laws and practices' International Institute for Economic Development, 2012, 9 - <http://pubs.iied.org/pdfs/G03443.pdf> on 4 January 2016.

⁴⁸ Ongugo P et al, 'Protecting traditional health knowledge in Kenya: The role of customary laws and practices' 9.

Kenya's Development Plan 1989-1993 recognised traditional medicine and made a commitment to enhancing the welfare of the practitioners.⁴⁹ The patent law of Kenya was amended in 1999 so as to include the protection of traditional medicines.⁵⁰ Thereafter there was the development of the Traditional Medicine and Medicinal Plants Bill and the National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions.

3.1.2 The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009

The Policy was put in place as a precursor to the enactment of a statute that addresses the protection of intellectual property rights that arise from the three categories. It recognises the manner in which traditional medicine was suppressed through the Witchcraft Act and as a result custodians are not properly rewarded for their practices and innovations from traditional knowledge.⁵¹ It provided a foundational legal framework upon which traditional medicine can be recognised and protected. One of its aims was to review and harmonise existing legislation on traditional medicine.⁵²

3.1.3 The Constitution of Kenya 2010

To begin with, the Independence Constitution of Kenya 1963 as well as the successive Constitution of 1969 did not lucidly provide for the entitlement of indigenous and local communities to protection and conservation of their indigenous knowledge. It did not envision such a situation especially in the realm of intellectual property.

The current Kenyan Constitution is rather commendable in many aspects specifically within the context of protection of the intellectual property rights of indigenous and local communities in Kenya. In fact, the Constitution recognises the link present between culture and the social, economic and development of a State. Accordingly, it upholds Culture as a pillar of our nation and society in its entirety.⁵³ Kenya prides itself in rich heritage owing to the fact that it comprises of people from many and distinct ethnic backgrounds each with different traditional beliefs and practices that distinguishes them from each other. These cultural practices have

⁴⁹ *Development plan, 1989–1993*, Government of Kenya, 1989.

⁵⁰ 'Legal status of traditional medicine and complementary/ alternative medicine: A worldwide review', WHO, 2001, 19 - <http://apps.who.int/medicinedocs/en/d/Jh2943e/4.html> on 10 January 2017.

⁵¹ Para. 1.1.6, *National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions*, Government of Kenya, July 2009.

⁵² *National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions*, Government of Kenya, July 2009.

⁵³ Article 11(2), *Constitution of Kenya* (2010).

contributed to the economic development of the State by being a means of sustenance to those communities and should therefore not be undermined and disregarded.

The Constitution obliges the State to recognise the contribution made by indigenous technologies⁵⁴ and promote the intellectual property rights of the people of Kenya.⁵⁵ It tasks Parliament with the mandate of ensuring that communities receive compensation in exchange for the use of their cultures.⁵⁶

The Constitution entitles persons whether individually or in communion with others to acquire and own property of any description, anywhere in Kenya.⁵⁷ It disapproves the enactment of law that allows the arbitrary deprivation of anyone of property⁵⁸ and the restriction of this right on a discriminatory basis.⁵⁹ In addition to this, it puts emphasis on the role of the State as a safe keeper of the intellectual property rights of the people of Kenya.⁶⁰

Finally, the State has a responsibility to safeguard and improve the intellectual property and indigenous knowledge arising from the biodiversity and the genetic resources of local communities.⁶¹

Traditional medicine is commonly but not necessarily limited to ownership by the community. It may also be attributed to an individual member of the community or several persons. It comprises of a physical dimension of property which is the actual plant or organism – biodiversity, used for medicinal purpose owned property but at the same time it is ‘spiritual’ because certain communities believe that a particular remedy was revealed to them by the spirits.⁶² The second characteristic is rather unique to indigenous and cultural knowledge. Traditional medicine therefore qualifies as a form of indigenous property and the law should protect the owners from the arbitrary deprivation of it. The protection of traditional medicine is currently warranted under intellectual property law and communities are entitled to royalties from the commercial exploitation of this property.

⁵⁴ Article 11(2) (b), *Constitution of Kenya* (2010).

⁵⁵ Article 11(2) (c), *Constitution of Kenya* (2010).

⁵⁶ Article 11(3) (a), *Constitution of Kenya* (2010).

⁵⁷ Article 40(1), *Constitution of Kenya* (2010).

⁵⁸ Article 40(2) (a), *Constitution of Kenya* (2010).

⁵⁹ Article 40(2) (b), *Constitution of Kenya* (2010).

⁶⁰ Article 40(5), *Constitution of Kenya* (2010).

⁶¹ Article 69(1) (c), *Constitution of Kenya* (2010).

⁶² Wekesa M, ‘Traditional knowledge- the need for *sui generis* system of IPRS protection’ in Intellectual property rights in Kenya, Konrad Adenauer Stiftung, 2009, 269- http://www.kas.de/wf/doc/kas_18323-1522-2-30.pdf?110214131039 on 10 January 2017.

3.1.4 The Protection of Traditional Knowledge and Cultural Expressions Act, 2016

Since the enactment of the 2016 Statute, Kenya has been regarded as one of the pioneering developing states in taking steps towards the effective protection of traditional knowledge and cultural expressions against biopiracy through the implementation of a *sui generis* regime. For a long time there have been discussions both nationally and internationally on the efficacy and the necessity of states implementing a completely new framework separate and somewhat different from the conventional ‘western’ regime for the purpose of protecting TK and TCEs. The inadequacy or otherwise of our current statute will be investigated in the next chapter of this paper.

One of the most salient features of this Act is the provision for the establishment of a Traditional Knowledge Digital Repository for the purpose of documenting information that has been collected by the county governments.⁶³ The county governments are expected to maintain registers of TK and TCEs that are collected and registered and these should ideally supplement the Repository.⁶⁴

Another outstanding feature of the new statute is that it provides for somewhat perpetual protection of indigenous knowledge⁶⁵ and cultural expressions subject to the retention of its characteristics. For instance, traditional knowledge will be protected provided it is intergenerational within a community; individually or collectively generated; characteristic to a specific community and it is intrinsic to the preservation of the culture of a community which is recognised as the holder or the custodian of it.⁶⁶

This is a significant expansion of the intellectual property rights framework seeing that the current intellectual property rights are granted by the State subject to a limitation in the term or duration of ownership. This ‘perpetuity’ may raise questions of whether this is anticompetitive or a creation of monopolies over traditional medicine which may be harmful to the economic development of the State. This can be rebutted by understanding that the origin and association of traditional medicine to a particular community gives it the attractive quality that qualifies it for protection. If anything, this quality significantly contributes to its cultural value.

⁶³ Section 8(3), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁶⁴ Section 8(1), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁶⁵ Section 13, *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁶⁶ Section 6, *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

The statute upholds the moral rights of owners of traditional medicine - owners are entitled to recognition for it, protection from false claims of origin by other parties and this traditional medicine should not be treated in a manner that prejudices the integrity of the custodian community.⁶⁷ Moral rights exist in perpetuity and communities cannot waive them.⁶⁸

The Act is tailored to reflect the devolved nature of the government of Kenya. It allocates roles and responsibilities to both the county and national governments. The county government (through the county executive member in charge of matters pertaining to culture) is tasked with the collection and compilation of information relating to TK and TCEs for purpose of documentation and storage in the Repository.⁶⁹ On the other hand, the national government acting through the Kenya Copyright Board (KECOBO) has a duty to establish and maintain the Repository.⁷⁰

Finally, the statute underscores the requirement for prior informed consent of the owners of the traditional knowledge and the community as a whole before registration of the indigenous knowledge by the county government⁷¹ and before a person exploits it.⁷² Prior informed consent as defined in the Act refers to *the giving of, by the prospective user, complete and accurate information, and based on that information, the prior acceptance, by the owners, to the use of their traditional knowledge or cultural expressions*. At the root of the protests against biopiracy of traditional medicine was the issue of exploitation of natural resources without permission from the custodian community or the owners. The statute expressly requires that this be obtained and it further gives the owners the right to institute legal proceedings against such persons.⁷³

It makes provision for the entering into equitable benefit sharing agreements and authorised user agreements between the owners of traditional medicine and parties purporting to use such knowledge or practice for commercial benefit. A person seeking to commercially exploit them must consult with them and the owners can accept or refuse to authorise the use or exploitation.⁷⁴ It extends the scope of equitable remuneration to include non-monetary benefits

⁶⁷ Section 21(2), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁶⁸ Section 21(4), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016

⁶⁹ Section 4(1) (a) (i), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷⁰ Section 5 (a), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷¹ Section 7(3), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷² Section 19(2), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷³ Section 38(1), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷⁴ Section 32(1), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

while paying regard to the needs of the community⁷⁵ for example, building of a school for a community or contribution to their socio economic development while at the same time maintaining their cultural heritage.

The government also has a role with regard to exploitation. For instance, if the government feels that certain resources are not being sufficiently used by the owner, it may subject to the prior informed consent of the owners grant a compulsory license to a third party to allow exploitation.⁷⁶ The Cabinet Secretary is also tasked with registering authorised user agreements which are otherwise null and void.⁷⁷

3.2 GLOBAL AND REGIONAL LEGISLATIVE AND INSITUTIONAL FRAMEWORK FOR THE PROTECTION OF TRADITIONAL MEDICINE

3.2.1 The Convention on Biological Diversity (CBD) and the Nagoya Protocol

The coming into force of the CBD on 29 December 1993 was heavily fuelled by the fact that states recognised the importance of natural biological resources to the social and economic development of present and future generations and the necessity for fair and equitable sharing of benefits arising from their use.⁷⁸ The Convention was the first stride taken globally towards the protection of traditional knowledge of the indigenous communities of its Parties. The provisions particularly relevant to the issue of biopiracy are Article 3 and Article 8(j).

It is guided by the fact that its member states recognise that numerous indigenous and local communities have a close reliance on biological resources which are a source of their traditional lifestyles and the desire to equitably share the benefits arising from the use of traditional knowledge.⁷⁹

Article 3 of the Convention recognises that states, by virtue of their sovereignty, reserve the right to determine in accordance with their environmental policies, the exploitation of the natural resources within their territories while ensuring that the activities do not cause damage to the environment of other States or territories outside their national jurisdiction.⁸⁰

Article 8(j) outlines that each Contracting Party shall to the extent possible and appropriate:

⁷⁵ Section 24(2), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷⁶ Section 12(1), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷⁷ Section 35(2), *Protection of Traditional Knowledge and Cultural Expressions Act*, No. 33 of 2016.

⁷⁸ 'History of the Convention', CBD, - <https://www.cbd.int/history/> on 12 January 2016.

⁷⁹ Preamble, *Convention of Biological Diversity*.

⁸⁰ Article 3, *Convention of Biological Diversity*.

“Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”⁸¹

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (Nagoya Protocol) adopted on 29 October 2010 is aimed at fostering, the fair and equitable sharing of benefits arising from the exploitation of genetic resources through transparent means.⁸² It aims to implement Article 8(j) of the CBD. It is however yet to enter into force.

3.2.2 The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement does not recognise traditional knowledge as a form of intellectual property. This is evident in Article 1 which limits intellectual property under the Agreement to copyright and related rights, trademarks, geographical indications, industrial designs, patents, lay-out designs and trade secrets.⁸³

3.2.3 Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization (ARIPO)

The Swakopmund Protocol is an initiative of member states of the ARIPO adopted on 9 August 2010. The Kenyan legislation heavily borrows from this Protocol particularly the provisions on duration and criteria for protection. The purpose of Swakopmund Protocol is primarily the protection of the rights of holders of traditional knowledge from infringement and the prevention of misappropriation of traditional knowledge and expressions of folklore.⁸⁴ It requires the setting up of a National Competent Authority responsible for implementing it.⁸⁵ Kenya is yet to do this but presumably KECOBO has played a huge role ensuring the implementation of the Protocol.

⁸¹ Article 8(j), *Convention of Biological Diversity*.

⁸² Article 1, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity*, 29 October 2010.

⁸³ Article 1(2), *TRIPS Agreement*.

⁸⁴ Section 1, *Swakopmund Protocol*, 9 August 2010.

⁸⁵ Section 3, *Swakopmund Protocol*.

With regard to assignment and licensing of traditional knowledge, the Protocol specifically states that knowledge belonging to a traditional or local community may not be assigned.⁸⁶ Another provision of the Protocol is that ARIPO is allowed to settle any concurrent claims that may arise from communities of different states and it can be guided by the customary law, local information sources and alternative dispute resolution mechanisms or any other practical mechanisms.⁸⁷

The provision does not state all the circumstances under which the claims may be brought. For instance, what then happens if one of the communities is not a member state of ARIPO? Does it still have the authority to entertain such claims? Does the jurisdiction of ARIPO take precedence over that of the member states with regard to such matters? Under what circumstances can it be ousted? The Protocol fails to provide guidelines for such circumstances. This may bring about a problem especially because the Kenyan statute provides for dispute resolution mechanisms as well.

⁸⁶ Section 8(1), *Swakopmund Protocol*.

⁸⁷ Section 24(3), *Swakopmund Protocol*.

CHAPTER FOUR: A CRITIQUE OF THE KENYAN SITUATION AND A COMPARATIVE STUDY OF OTHER COUNTRIES

4.1 INTRODUCTION

This Chapter will begin by identifying the shortcomings and limitations presented by the current legislative and institutional framework of Kenya. It will thereafter analyse the situations in India, South Africa and Thailand to draw lessons and best practices which Kenya can emulate.

Before proceeding to the comparative analysis, it would be necessary to distinguish the two types of intellectual property protection that can be sought and thereby incorporated in different legislative frameworks. These are, defensive and positive protection. Defensive protection is a mechanism that prevents the acquisition of intellectual property rights and in this case,⁸⁸ right to traditional medicine from the onset. This is through creation of a database of traditional medicine as done in India. It is defensive to the extent that it prevents the filing of patents in traditional medicine because such medicine can be considered prior art because it is within the database and easily accessible to patent examiners in several offices. One of the criticisms presented against defensive protection is the failure to acknowledge or recognise the rights that a community has to the exploitation and utilisation of its traditional medicine and protection against its misappropriation.

Positive protection on the other hand enforces the rights of indigenous communities over their traditional medicinal knowledge by granting and recognising these rights legitimately. This enables them to control their knowledge and further reap the benefits of their commercial exploitation.⁸⁹ Positive protection in the form of a sui generis law may however not be effective because the legislation may only be enforceable within the country alone. As a result countries and organisations have been pushing for a singular international treaty⁹⁰ or alternatively the amendment of the TRIPS Agreement.

Kenya incorporates defensive and positive protection mechanisms within its Act by requiring the establishment of a Repository for the documentation of such knowledge and by recognising and purporting to uphold, protect and promote the rights of indigenous and local communities. India on the other hand has embraced a defensive approach by establishment of the Database.

⁸⁸ 'Traditional knowledge and intellectual property – Background brief', WIPO, - http://www.wipo.int/pressroom/en/briefs/tk_ip.html on 16 January 2017.

⁸⁹ 'Traditional knowledge and intellectual property – Background brief', WIPO.

⁹⁰ 'Traditional knowledge and intellectual property – Background brief', WIPO.

South Africa just like Kenya seems to be incorporating both approaches especially in the current Bill. Thailand and Portugal can be said to have incorporated a positive approach to protection through their sui generis regime.

4.2 KENYA

The 2016 Statute is indeed a welcome reform in the legal system. The Act is yet to be implemented therefore it is difficult to discuss its effectiveness or successes. On the face of it, some of the provisions of the Act may be too optimistic and possibly hard to achieve in the near future based on Kenya's social, economic and political situation.

The Act requires KECOBO, on behalf of the national government to establish a Digital Repository or rather a traditional knowledge database which will be used for the collection and documentation of indigenous knowledge and cultural expressions upon their registration by the county governments. This Repository will provide a database for prior art and a source of reference for parties seeking to patent pharmaceutical products that are sourced from already documented and protected indigenous medicine and medicinal practices.

The presence of traditional medicine in the Repository will automatically result in the disqualification of the patent application because the product will not qualify for novelty. While this is a much needed resource, convincing custodians of traditional medicine or the communities themselves to make 'public' their resources may prove to be difficult. They may refuse out of suspicion or lack of proper understanding of the purpose of collecting and registering such information. Acquiring their cooperation is a challenge in itself.

It is not surprising that pharmaceutical firms in developed states are reported to be infamous for patenting traditional medicine sourced from developing states. This Repository will be very effective if it is accessible to other nations as well especially when it comes to international patent applications.

Another concern relating to the Depository is the financial issues surrounding the establishment and maintenance. It may be rather costly to maintain it.

The KECOBO is an institution formed under section 3 of the Copyright Act and its functions are outlined under section 5 of the Act. It is mandated to direct, co-ordinate and oversee implementation of laws and international treaties ratified by Kenya relating to copyright and related rights; licensing and supervision of activities of collective management societies; the education of the public on matters pertaining to copyright and related rights and the

maintenance of a database on authors and their works.⁹¹ Broadly speaking, they are tasked with simultaneously overseeing the promotion of copyright and related rights and the protection of the authors and copyright holders from infringement of their rights.

The Protection of Traditional Knowledge and Cultural Expressions Act somewhat widens the mandate of KECOBO to the realm of indigenous knowledge. This seems advantageous seeing that the institution has been in place and active for the longest time and the likelihood that it will deliver the objectives of the statute in a timely manner is high. KECOBO as the name suggests comprises of experts primarily in the area of copyright and related rights and not necessarily traditional knowledge and cultural expressions.

KECOBO should perform the statutory required tasks in the interim but it would be advisable for the Statute to make further provision for the establishment of an institution other than the KECOBO whose scope exclusively pertains to the management and documentation of indigenous knowledge and cultural expressions under the Act. It should comprise of experts with a depth of knowledge or specialisation in the different forms of this knowledge and cultural expressions.

The transitional provisions of the Statute provide for continuity of agreements entered into by the indigenous and local communities and persons wishing to exploit their natural resources prior to the commencement of the Act. It however does not state whether communities can seek recourse for the unfair exploitation or misappropriation of their traditional medicine and medicinal plants without their prior informed consent and without receipt of compensation due to them if it happened before the commencement of the Act. It does not state whether the Act can be applied retroactively in such a case.

4.3 SOUTH AFRICA

South Africa is another developing nation where the majority of populations still heavily relies on traditional medicine and medicinal practices for primary healthcare as opposed to the orthodox form of treatment. On 10 December 2013, the President of South Africa assented to the Intellectual Property Laws Amendment Act which led to amendments in the then intellectual property law framework in order to provide for protection of indigenous knowledge as opposed to enacting a sui generis law dedicated to protection of indigenous knowledge. The

⁹¹ Section 5, *Copyright Act*, No.12 of 2001.

Act required statutory provision for a National Council for Indigenous Knowledge primarily with advisory functions.⁹²

The Act also provided for the establishment of a National Trust and Fund for Indigenous Knowledge to facilitate among other things the commercialisation and exploitation of indigenous knowledge and cultural expressions in order to generate income.⁹³ Finally the Act provides for the establishment of a National Database for indigenous knowledge to be kept at the registrars of patents, copyright, trademarks and designs.⁹⁴

In 2016, the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill was enacted and is yet to be enforced. The Bill provides for the establishment of the National Indigenous Knowledge Systems Office (NIKSO) mandated to protection, recognition and development of indigenous knowledge; facilitating the restitution of communities which have been previously deprived of their rights and benefits from indigenous knowledge and assisting indigenous communities in negotiating benefit sharing agreements.⁹⁵

One of the controversial provisions of the Bill is section 5 which will require the mandatory accreditation and certification of people purporting to be traditional medicine practitioners by NIKSO.⁹⁶ This application can be referred to an agent who is competent in matters of traditional medicine for assessment.⁹⁷

Another controversial part of the Bill is chapter 7 on the commercial utilisation of indigenous knowledge and enforcement of rights. This has been contested on the grounds that it will greatly contribute to ethno-piracy with the State reaping a higher percentage from the resource benefit sharing agreements than the actual custodians of traditional medicine which is the community.⁹⁸

4.3 INDIA

India is notably one of the countries known for the multiplicity in its genetic resources commonly used for traditional medicine. Some of the commonly known systems in existence

⁹² Section 4, *Intellectual Property Laws Amendment Act*, No. 28 of 2013 (South Africa).

⁹³ Section 4, *Intellectual Property Laws Amendment Act*, No. 28 of 2013 (South Africa).

⁹⁴ Section 4, *Intellectual Property Laws Amendment Act*, No. 28 of 2013 (South Africa).

⁹⁵ Section 5, *Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill*, 2016 (South Africa).

⁹⁶ Section 14(1), *Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill*, 2016 (South Africa).

⁹⁷ Section 14(2), *Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill*, 2016 (South Africa).

⁹⁸ 'Will SA government protect our indigenous medicine' Academy for Environmental Leadership SA-<http://www.afel.co.za/will-sa-government-protect-our-indigenous-medicine/> on 13 January 2017.

for centuries are Ayurveda, Siddha and Unani.⁹⁹ Following discoveries of gross bioprospecting and biopiracy of natural remedies by foreign companies, the Indian government licensed 200,000 local treatments as public property, for local use but not for sale.¹⁰⁰

Following the adoption of the CBD in 1992, the Biodiversity Act was enacted in 2002 in order to protect biodiversity and effectively implement the objectives of the convention. The Act regulates the use of biological resources and the associated knowledge whether for commercial use or research purposes. The implementation of the Act is further supported by the National Biodiversity Authority (NBA) an autonomous body which was established in 2003 in order to facilitate, advise and regulate activities relating to biodiversity.

India amended its Patent Act 1970 expanding the grounds for opposition or revocation of a patent on the basis that the invention claimed already exists in the domain of traditional knowledge.¹⁰¹ In 2001 the Traditional Knowledge Digital Library (TKDL) was set up in India in a bid to prevent misappropriation of the country's traditional medicinal knowledge. Numerous patents were being wrongfully granted at international offices.¹⁰²

Even after the setting up of TKDL it was discovered that patents were still wrongfully granted because the medicinal knowledge was only available in the local languages of Sanskrit, Arabic and Urdu among others. This information was therefore not accessible or understandable by patent examiners at international patent offices hence the continued granting of patents wrongfully. India however overcame this language barrier by translating the resources on all Indian traditional medicines and medicinal practices to English, Japanese, French, German and Spanish through use of modern technology as well as a classification system referred to as the Traditional Knowledge Resource Classification (TKRC).¹⁰³

India entered into TKDL Access agreements which are non-disclosure, with nine International Patent Offices namely the European Patent Office, US Patent and Trademark Office, Japan Patent Office, United Kingdom Patent Office, Canadian Intellectual Property Office, German Patent Office, Intellectual Property Australia, Indian Patent Office and Chile Patent Office.

⁹⁹ WHO, *Legal status of traditional medicine and complementary/alternative medicine: A worldwide review*, 131.

¹⁰⁰ 'India moves to protect traditional medicines' 13(7) *Bridges Weekly Trade News Digest*, 3, 25 February 2009-
<http://www.ictsd.org/sites/default/files/review/bridgesweekly/bridgesweekly13-7.pdf> on 10 January 2017.

¹⁰¹ Dewan, Mohan, 'The Realities of Traditional Knowledge and Patent in India, Intellectual Property' Watch, 27 September 2010-
<http://www.ip-watch.org/weblog/2010/09/27/the-realities-of-traditional-knowledge-and-patents/> on 13 January 2017.

¹⁰² 'Protecting India's traditional knowledge' WIPO Magazine, June 2011-
http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html on 13 January 2017.

¹⁰³ <http://www.tkdl.res.in/tkdl/LangDefault/Common/Abouttkdl.asp?GL=Eng> on 13 January 2017.

These nine offices can access the TKDL while examining whether there is prior art in a patent application made.

The accessibility of the TKDL has been successful to the extent that over 200 international patent applications of pharmaceutical companies have been rejected, cancelled, withdrawn or amended based on the information available in the TKDL.¹⁰⁴ Applications from companies such as Johnson & Johnson in the USA and Unilever, Netherlands have been defeated.¹⁰⁵

Although the TKDL has been effective as a defensive form of protection by preventing the granting of applications, it has been criticised because it still does not acknowledge the legal right of the traditional medicine holder.

Another limitation faced by TKDL and possibly other databases is that it is impossible to record all the information,¹⁰⁶ particularly traditional medicinal knowledge that was orally transmitted. The TKDL transcribes knowledge that is already written on the traditional medicinal systems. In addition to this, the setting up of the TKDL was a costly affair. It is reported to have costed approximately Rs. 1.18 crore which is equivalent to over US\$ 26 million, an amount not easily available to developing countries.¹⁰⁷

4.4 THAILAND

Thailand, one of the countries that embraces the sui generis regime provides for statutory protection for traditional medicinal knowledge through the Protection and Promotion of Traditional Thai Medicinal Intelligence Act which was enacted in 1999. The statute categorises Thai traditional medicinal intellectual property rights into three for purposes of protection. These are: national formula, general formula and personal formula.¹⁰⁸

Traditional medical knowledge which is deemed to be of great value to public health can be declared national formula and is considered to be in the public domain.¹⁰⁹ Persons can acquire licenses to register or use national traditional medicine for the production of drugs, research or

¹⁰⁴ 'TKDL outcomes against bio-piracy'- <http://www.tkdil.res.in/tkdil/LangDefault/Common/TKDLOutcome.asp?GL=Eng> on 13 January 2017.

¹⁰⁵ 'TKDL success against MNC'- <http://www.tkdil.res.in/tkdil/LangDefault/Common/Mnc.asp> on 13 January 2017.

¹⁰⁶Udgaonkar, Sageeta, 'The recording of traditional knowledge: Will it prevent "Biopiracy"?' 82(4) *Current Science*, February 2002, <http://www.ias.ac.in/currsci/feb252002/413.pdf> on 13 January 2017.

¹⁰⁷ Avilia D, 'Traditional knowledge database: A defensive measure against traditional knowledge cross border misappropriation' Unpublished Master Program in Law and Technology Thesis, Tilburg University, North Brabant, 52.

¹⁰⁸ Section 16, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹⁰⁹ Section 17, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

commercial exploitation.¹¹⁰ General formula is that traditional medicine is deemed to have been widely used and whose protection has expired.¹¹¹ It is deemed to be medical knowledge commonly known and also within the public domain. On the other hand, registration of personal formula results in the grant of exclusive intellectual property rights to the holders.¹¹² The Act guarantees protection to the owners during their lifetime and an additional 50 years after their death.¹¹³

It is interesting to note that the Act implements the reciprocity principle under TRIPS by extending intellectual property protection to foreigners for local traditional medicine where they permit persons of Thai nationality to protection of their rights to Thai traditional medicine.¹¹⁴

The Act establishes the Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence which comprises of persons holding relevant offices in departments such as intellectual property rights, forestry, livestock agriculture, medical sciences, food and drug administration and environmental policy and planning.¹¹⁵ Such people must possess relevant experience in Thai traditional medicine. The Act also establishes the Institute for Traditional Thai Medicine mandated to promote education, training, research, studies and development of intelligence on traditional Thai medicine.¹¹⁶

4.5 PORTUGAL

In pursuit of fulfilment of the obligation under Convention for Biological Diversity, Portugal enacted Decree-Law No. 118/2002 as a means of protecting and promoting traditional knowledge as a safeguard for plant varieties and genetic resources.

According to the Decree TK includes *all intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a*

¹¹⁰ Section 19, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹¹¹ Section 18, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹¹² Carvalho N, 'From the Shaman's hut to the patent office: In search of effective protection for traditional knowledge', 92- <https://law.wustl.edu/centeris/Papers/Biodiversity/PDFWrdDoc/Fromshaman2.pdf> .

¹¹³ Section 33, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹¹⁴ Section 43, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹¹⁵ Section 5, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

¹¹⁶ Section 12, *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*, B.E. 2542, 1999 (Thailand).

*non-systematic manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations.*¹¹⁷

It provides protection against the misappropriation and reproduction of TK where it has been registered in the Register of Plant Genetic Resources (RRGV) but also extends protection to owners who wish to keep their TK confidential.¹¹⁸ The duration of protection is 50 years from the time of application subject to renewal for another 50 years.¹¹⁹ Any entity may seek registration provided it represents the interests of the geographical area where the traditional medicine is widely found.¹²⁰ This means that applicants can be individuals, communities or companies.

Some of the outstanding limitations of protection under the Portugal Decree is the duration for protection which is a renewable term of 50 years. At the same time, it has been argued that protection need not be perpetual. The essence of traditional medicinal knowledge is derived from the culture of the community that owns it. The absence of culture results in the absence of the uniqueness of traditional medicine.¹²¹ This can however be rebutted if it is viewed as something that transcends generations. Unlike most laws, the Decree does not require substantive examination prior to protection thus facilitating the process of application and registration. It should be noted that the Decree does not afford protection to all TK associated with all biological resources.¹²²

¹¹⁷ Article 3.1, *Decree- Law No. 118/2002*, 20 April 2002 (Portugal).

¹¹⁸ Article 3, *Decree- Law No. 118/2002*, 20 April, 2002 (Portugal).

¹¹⁹ Article 3.6, *Decree- Law No. 118/2002*, 20 April 2002 (Portugal).

¹²⁰ Article 9.1 (a), *Decree- Law No. 118/2002*, 20 April 2002 (Portugal).

¹²¹ Carvalho N, 'From the Shaman's hut to the patent office: In search of effective protection for traditional knowledge' 93.

¹²² Carvalho N, 'From the Shaman's hut to the patent office: In search of effective protection for traditional knowledge' 93.

CHAPTER FIVE: CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

This study has examined the legal, regulatory and institutional framework that governs the protection of traditional medicine as an intellectual property right. It has looked at the situation in India, South Africa, Thailand and Portugal alongside Kenya while attempting to establish the best way forward. This study has aimed at answering the following questions:

- a. Whether the current legislative framework or the sui generis regime is adequate in the protection and promotion of traditional medicine
- b. Whether the inadequacy is likely to contribute to biopiracy

The enactment and coming into force of the new Statute in Kenya has indeed ushered in the dawn of a new era for traditional medicine. At the same time, this legislation may prove to be insufficient due to certain discrepancies within the provisions and inadequacies. The lack of an international treaty to govern this type of intellectual property makes it even more difficult. As a result of the loopholes within the provisions of the Statute, indigenous and local communities will continue falling victim to the misappropriation and unfair exploitation of their cultural heritage and intellectual property.

5.2 RECOMMENDATIONS

Generally, the legislative framework should be reviewed in order to fully appreciate the importance of traditional medicinal knowledge. I would highly propose the following changes to the legislative, regulatory and institutional framework for traditional medicine as a form of traditional knowledge as a way forward:

- a. The establishment of an institution separate and distinct from KECOBO constituting relevant expertise or experience in the area of traditional knowledge and cultural expressions. In this case, it would be important to have an institution of people who have knowledge in matters pertaining to the environment, food and medicine and agriculture. The institution can then be mandated with the protection and promotion of all forms of traditional knowledge and the safeguarding of the interests of the indigenous and local communities.
- b. Allocation of resources towards the development and maintenance of the Digital Repository.
- c. The Repository once established should be made available to international patent offices in order to prevent the filing of patents in traditional medicine that is held by

indigenous and local communities in Kenya in other countries. This would require the entering into agreements with those international patent offices. Best practice in this case can be emulated from India. The Repository should be made available online.

- d. Review of the legislation in order to expressly provide for biopiracy as an offence and bioprospecting.
- e. Education and training of indigenous and local communities on the importance of allowing the government to assist in the protection and promotion of traditional medicine.
- f. Respecting indigenous and local communities who wish to keep their traditional medicinal knowledge confidential rather than register and document it but still according them sufficient protection as is the case in Portugal.

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