CRITICAL ANALYSIS INTO THE PROTECTION OF TRADITIONAL MEDICAL KNOWLEDGE IN KENYA: LESSONS FROM INDIA AND PERU

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DECLARATION

I, KAMANGA SYLVIA KASUVU, 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, 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 a University Supervisor.

Signed: .....

DR. ISAAC RUTENBERG

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List of Abbreviations

TK	Traditional Knowledge
TCE'S	Traditional Cultural Expressions
ILC's	Indigenous and Local Communities
CBD	Convention on Biodiversity
CSIR	Council for Scientific and Industrial Research
IP	Intellectual Property
IPR's	Intellectual property rights
NBA	National Biodiversity Authority
TKDL	Traditional Knowledge Digital Library
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
IPC	International Patent Classification
TKRC	Traditional Knowledge Resource Classification
UPOV	International Union for the Protection of New Varieties of Plants
INDECOPI	The National Institute for the Defense of Competition and Intellectual Property
WIPO	World Intellectual Property Organisation
WHO	World Health Organisation
UNEP	United Nations Environmental Programme
US	United States
ARIPO	African Regional Intellectual Property Organization

List of Legal Instruments

Legislations

Constitution of Kenya, 2010

Protection of Traditional Knowledge and Cultural Expressions Act (Act, No. 33 of 2016.)

Copyright Act, (Act no. 12 of 2001)

Constitution of the United States of America, 1787.

Biological Diversity Act, 2002 (Act No. 18 of 2003) – India

Plant Varieties and Farmers' Rights Act, (Act No. 53 of 2001)- India

Patents (Amendment) Act, 2002 (Act no, 38 of 2002)- India

Law Introducing A Protection Regime for The Collective Knowledge of Indigenous Peoples Derived from Biological Resources, 2002, (Law no. 27811)-Peru

International and Regional instruments

Berne Convention for the Protection of Literary and Artistic Works, May 4 1896, UNTS 828 (p.221).

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

Convention on Biodiversity, 5 June 1992, United Nations Treaty Series, vol. 1760, p. 79.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 29 October 2010, UNEP/CBD/COP/DEC/X/1

Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization (ARIPO), 9 August 2010.

Indigenous and Tribal Peoples Convention, 27 June 1989, C169

ABSTRACT

The practice of traditional medicine amongst communities has taken place from time immemorial. Such practices are so engrained to the culture and identity of the communities that lack of recognition and protection would be a great injustice to the communities. Traditional medicine have had such a great impact, especially in Africa. This is because, for a long time it was and, in some parts, remains to be the primary source of healthcare for many. Over recent years, there has been a shift towards the use of natural resources for the production of medicine by the western world. This has led to unlawful exploitation of indigenous communities' traditional knowledge especially in third world countries. In response, there has been debate over how traditional medicine and traditional knowledge as a whole can be protected for the benefit of the local communities. Many have agreed that due to the dynamic nature of traditional knowledge there is need for a sui generis regime to efficiently protect these practices. Kenya is one of the countries that has taken the bold step of providing a sui generis legislation, The Protection of Traditional Knowledge and Cultural Expressions Act. This study seeks to critically analyse the new legislation to establish its efficiency in protecting traditional medical knowledge. Furthermore, it will provide recommendations for its improvement based on best practices adopted in other jurisdictions such as India and Peru.

1. CHAPTER ONE: INTRODUCTION

1.1 BACKGROUND

Traditional knowledge is defined as "any knowledge originating from an individual, local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, embodied in the traditional lifestyle of a community;[1] or knowledge 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."[2]

The importance of Traditional Knowledge came to light due to globalisation. It is undeniable that traditional knowledge is contributing to production in today's economy.[3] This comes as a result of the shift towards the production and use of traditional goods and services.[4]

Traditional knowledge can be subdivided into two aspects: Traditional Medical Knowledge and Traditional Cultural Expressions (TCEs)/Expressions of Folklore.[5] For the purposes of this study, we shall concentrate on the aspect of traditional medical knowledge.

Traditional medicine refers to "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses"[6]

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[1] Section 2(a), *Protection of Traditional Knowledge and Cultural Expressions* (Act, No. 33 of 2016).
[2] Section 2(b), *Protection of Traditional Knowledge and Cultural Expressions* (Act, No. 33 of 2016).
[3] Tawanda M, 'Knowledge and Power: Law, Politics and Socio-cultural Perspectives on the Protection of Traditional Medical Knowledge Systems in Zimbabwe' in Mackmillan F, 5eds '*New Directions in Copyright Law'* Edward Elgar Publishing,2006.
[4] Tawanda M, 'Knowledge and Power: Law, Politics and Socio-cultural Perspectives on the Protection of Traditional Medical Knowledge Systems in Zimbabwe' (2006)
[5] Wekesa M, 'Traditional Knowledge- The need for Sui generis System of Intellectual Property Rights Protection' in Intellectual Property Rights in Kenya' Konrad Adenauer Stiftun, 2009.
[6] World Health Organisation, 'Policy perspectives on medicine: Traditional medicine-growing, needs and potential'

A study by the World Health Organization reveals that approximately 80% of the emerging world's population is relies on medicinal plants for treatment of their illnesses. [7] This comes as a result of traditional medicine being the only form of healthcare available in rural populations as well as the most cost-effective option.[8] An illustration of these plants includes *Toddalia asiatica*, a plant native to Swaziland is prepared and used to treat abdominal pains, coughs and sore throat.[9]

The question on the protection of traditional knowledge is source of a debate both regionally and internationally.[10] The enactment of the Protection of Traditional Knowledge and Cultural Expressions Act in Kenya is an effort by the State in fulfilling its obligations as provided in the constitution..[11]

Traditional knowledge as a whole is essential as it symbolizes the origins of the community. Traditional medicine, from the definition given above, is protected under the realm of intellectual property rights. However, a challenge arises due to the communal aspect of traditional medicine. Difficulties arise in identifying an owner and custodian of the rights as these traditions are passed down through the generations and shared amongst members of the community. This poses a challenge to intellectual property laws in protecting them as intellectual property rights accrue on an individualistic basis.[12]

The challenges that arose from protecting traditional medicine under intellectual property rights has resulted in cases of exploitation of communities as well as dilution of the cultures and practices by foreigners without the due remuneration of the communities.

Cases of this include the Neem tree which is predominantly grown in India. It is now known for its use in toothpaste, detergents and pesticides. The US Department of Agriculture in conjunction

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[7] World Health Organisation (WHO), 'Guidelines for Registration of Traditional Medicine in the African Region' - https://www.afro.who.int/publications/guidelines-registration-traditional-medicine-african-region- accessed on 30 May 2019.
[8] Mahomoodally M, 'Traditional Medicine in Africa: An Appraisal of Ten Potent African Medicinal Plants',1, *Evidence-Based Complementary and Alternative Medicine.*2013,
[9] JA Orwa et al. 'The use of Toddalia asiatica (L) Lam. (Rutaceae) in traditional medicine practice in East Africa', *Journal of Ethnopharmacology*, 2008. -< http://www.ethnopharmacologia.org/prelude2016/pdf/biblio-ho-09-orwa.pdf>- on 30 May 2019.
[10] Ouma M, 'Traditional knowledge: the challenges facing international lawmakers', World Intellectual Property Organisation, 2017.
[11] Article 11(3) and 61, *Constitution of Kenya* 2010.
[12] Wekesa M, 'Traditional Knowledge- The need for Sui generis System of Intellectual Property Rights Protection' in Intellectual Property Rights in Kenya' Konrad Adenauer Stiftun, 2009.276.

with a pharmaceutical company filed and was granted a patent for the agent found within the plant. However, after a few years the Indian government brought a claim in an effort to safeguard its farmers, biodiversity and traditional knowledge that was used by foreign nationals. After examination by the European Patent Office, the patent was annulled based on grounds of lack of uniqueness and inventive step.[13]

An example closer home was that regarding Bayer, a German firm dealing with pharmaceuticals are said to have used biological material in the manufacturing of a drug named *Glucobay* found in Central Kenya. Till this day, there has not been any remuneration given to Kenya or an agreement for benefit sharing made.[14]

1.2 STATEMENT OF PROBLEM

The practice of traditional knowledge and traditional medicine, in particular, have been part of African culture for generations. Its communal and trans-generational nature has allowed it to grow and develop within communities. However, with the coming of the global and capitalistic world, these practices have fallen into the hands of the western world and with it, economic exploitation of biodiversity in third world countries such as Kenya. Intellectual property rights have been the major source of protection for cultural knowledge in most parts of the world including Kenya. Recently, the Protection of Traditional Knowledge and Cultural Expressions Act was enacted by Kenya. The Act sought to protect traditional knowledge including traditional medicine through the provision of a *sui generis* framework. However, the Act suffers from a few cases of ambiguity which if not corrected may contribute to the inefficient protection of traditional medical knowledge in Kenya.

[13] Shiva V, 'The neem tree - a case history of biopiracy',Third World Network- https://twn.my/title/pir-ch.htm- accessed on 30 May 2019.
[14] Edmonds Institute, 'Out of Africa: Mysteries of Access and Benefit Sharingon',2006,1.

1.3 JUSTIFICATION OF STUDY

The use and development of traditional medical knowledge is essential in Kenya for various reasons; it acts as the primary healthcare option to many communities in Kenya, it serves as a symbol of identity for the communities that discovered and used them as part of their culture and recently has become economically beneficial with the increase in commercialization of traditional medicine by pharmaceutical firms.[15] Therefore, it is important to protect traditional medicine to ensure the economic and social development of communities in Kenya. To do this, it is essential to curb the economic exploitation of traditional knowledge that leads to the loss of revenue and the infringement of the rights of the communities. This study seeks to solve this issue by identifying inconsistencies with the current law and highlighting mechanisms that have been adopted in other jurisdictions that can help Kenya achieve its goal.

1.4 STATEMENT OF OBJECTIVES

a) Highlight the effects of insufficient protection of traditional knowledge on the traditional communities.

b) To analyze the current Act concerning traditional knowledge and establish if it is efficient for its function.

c) To identify means to overcome the economic exploitation of traditional medicine for the communities' benefit as well as the benefit of the state.

1.5 RESEARCH QUESTIONS

a) What is the current legislative framework handling issues of economical exploitation of traditional knowledge?

b) Are there any gaps that exist within the legislative framework that make the protection of traditional medical knowledge inefficient?

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[15] Ouma M, 'The policy context for a commons approach to traditional knowledge in Kenya' in Beer J, Armstrong C, Oguamana C & Schonwetter T (ed) , *Innovation & Intellectual Property: Collaborative Dynamics in Africa*, University of Cape Town Press, South Africa, 2014.132.

c) What lessons can be applied from other jurisdictions to better protect traditional medical knowledge?

1.6 HYPOTHESIS

The Protection of Traditional Knowledge and Cultural Expressions Act has gone a long way in the protection of traditional Knowledge. However, it needs some amendments to make it more efficient.

1.7 RESEARCH DESIGN

1.7.1 Research methodology

The following study relies on qualitative research. The main research methodology used is secondary data from books, journals, cases, statutes, scholarly articles, reports and online databases on the subject.

1.7.2 Assumptions

The study works on the assumption that all local communities are indigenous.

1.7.3 Limitations

The main limitation would be that of time constraints.

1.7.4 Chapter breakdown

Chapter 1: Provides an introduction to the topic of traditional medical knowledge and the problems associated with it.

Chapter 2: Provides a theoretical framework for the protection of traditional medical knowledge based on Labor theory, Utilitarianism and Person-hood theory.

Chapter 3: Conducts an in-depth analysis of the legal framework governing traditional medical knowledge from a national and international perspective and the problem of its exploitation.

Moreover, it will highlight the inefficiencies of the Protection of Traditional Knowledge and Cultural Expressions Act.

Chapter 4: Will provide a comparative analysis of the protection of Traditional knowledge in India and Peru and provide similarities and differences in their systems

Chapter 5: Will provide a summary of the analyses that have taken place in the research paper and provide recommendations based on the findings.

2. THEORETICAL FRAMEWORK BASED ON THE JUSTIFICATION FOR INTELLECTUAL PROPERTY RIGHTS.

Introduction

This study shall make use of three theories; Utilitarianism, personhood theory and Locke's labour theory as the justification for the protection of traditional medical knowledge. These theories have been chosen as they advocate for property rights to be accrued to intellectual property rights holders based on various factors. They have also been selected as they have extensively been developed to cater for Intellectual Property Rights.

2.1. Labour theory (Lockean theory)

This theory was first propounded by John Locke who provides that mankind may use labour to determine their rights over natural resources, and impose a moral duty on others to honor said rights.[16] The theory is set in a state of nature where he observes that God gave the world and its resources to men in common.[17] These goods have been given to man for his enjoyment. However, this cannot be done in their natural state.[18] Thus he observes "The labour of his body and the work of his hands, we may say, are strictly his. Therefore, when he takes something from the state that nature has provided and left it in, he mixes his labour with it, thus joining to it something that is his own; and in that way, he makes it his property."[19] This means that man is entitled to the work or outcome from the fruits of his labour and is free to enjoy it to the exclusion of others.

In the case where labour has been expended with others, each person has a right to ownership over that right. In the case of protection of intellectual property rights, it is justified on the basis that ideas and expressions of the mind constitutes intellectual labour. Therefore, they should be protected.

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[16] Prassana A, 'John Locke's Labour Theory: A Justification of IPRs', Legal Services India. - http://www.legalservicesindia.com/article/2536/John-Locke%E2%80%99s-Labour-Theory:-A-Justification-of-IPRs.html- on 30 May 2019.
[17] Locke J, '*Second Treatise of Government'*, (18ed) Hackett Publishing. Company, Indianapolis,1980,115.
[18] Moore A, 'Lockean theory of Intellectual Property', 21, *Hamline Law Review*, 1997,67.
[19] Locke J, '*Second Treatise of Government'*, (18ed) Hackett Publishing. Company, Indianapolis,1980,115.

Locke's theory can be proved through the avoidance theory of labour. This provides that Labor in itself tends to be an unpleasant and uncomfortable situation. Locke himself goes as far as referring to labour as pain.[20] Thus, most people will tend to avoid it. Therefore, those who sacrifice and choose to labour should be accorded appropriate rewards through the ownership of property.[21]

Another justification of Lockean theory is through the 'value-added' labour theory. The theory holds that if someone produces something that is of value to others, that it goes beyond the expectations of morality then the person deserves to be rewarded for his efforts.[22] This justifies the use of patent law as it is the value one adds to the society that is rewarded.[23]

The protection of traditional medical knowledge can be justified on the basis of the two interpretations of the theory. The local and indigenous communities that discovered the plants and medicine by expending some form of labour. Thereby they sacrificed their comfort to establish traditional medicine. Furthermore, the discovery of these medicine has added value to society as they have been used in the development of drugs for the treatment of illnesses as well as contributed to the development of the economy. Therefore, they deserve to be rewarded for their efforts through the attainment of property rights. Moreover, they deserve to obtain remuneration for their discoveries and traditional practices. This can be achieved through the use of access and benefit-sharing agreements.

Locke's theory of property accrues property rights on the owner. They include, the right to appropriate, to transfer and to exclude others from using it.[24]These rights can be applied to the local and indigenous communities' right to restrict the use of the medicine from others with the exception of if they give consent for its use and are adequately rewarded for it.

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[20] Kramer M, '*John Locke and the Origins of Private Property: Philosophical Explorations of individualism, community and equality*', Cambridge University Press,1997,173.
[21] Hughes J, 'The Philosophy of intellectual property', 77, *Georgetown Law Journal,*1988.
[22] Mossof A, 'Saving Locke From Marx: The Labor Theory Of Value In Intellectual Property Theory', 29, *Journal of Social Philosophy & Policy*, 2, 2012,4.
[23] Cwik B, 'Labor as the Basis for Intellectual Property Rights', 17, *Ethical Theory and Moral Practice,* 2013.
[24] Snyder D, 'Locke on Natural Law and Property Rights', 16, *Canadian Journal of Philosophy,* 1986, 734.

Critics of this theory propound that the fact that intellectual property rights are limited to factors such as time limits prove the fact that they are not property rights.[25]

2.2 Utilitarianism

This is based on the thinking that actions are good if they provides happiness to the greatest number of people. The theory was established by Jeremy Bentham. According to him, people were ruled by 2 masters; pleasure and pain. From this, he established the principle of utility which acted as a standard of the right action or a wrong one.[26] The social value of utilitarian works relies solely on one's ability to perform tasks.[27] In terms of intellectual property, industrial progress and cultural goods have a beneficial effect on society. Consequently, in order to promote the inventions and creations, the state has to ensure that the benefit will be greater than the cost.[28] The Constitution of the United States provides for the creation of Intellectual property rights such as patents and copyright on a utilitarian foundation, "to Promote the Progress of Science and useful Arts."[29] The social benefit of intellectual property rights is further provided in the case of *Mazer v Stein*. They observed that "The enactment of copyright legislation by Congress under the terms of the Constitution is not based upon any natural right that the author has in his writings, ... but upon the ground that the welfare of the public will be served by securing to authors for limited periods the

[25] Mossof A, 'Why Intellectual Property Rights? A Lockean Justification' 2015, -https://www.lawliberty.org/liberty-forum/why-intellectual-property-rights-a-lockean-justification/- on 30 May 2019.
[26] Bentham, J, '*An Introduction to the Principles of Morals and Legislation'.*, Oxford: Clarendon Press, 1789,1907
[27] Menel P, 'Intellectual Property: General Theories', *Berkeley Centre for Law and Technology*,1999,129.
[28] Oddi S, 'Un-Unified Economic Theories of Patents - the Not-Quite-Holy Grail', 71 *Notre Dame Law Review*,1996,274.
[29] Article 1 Section 8, *Constitution of the United States of America.*

exclusive rights to their writings."[30] The purpose of the limited period of ownership is to prevent the development of monopolies which would hinder innovation.

In terms of traditional medical knowledge, their protection is essential as it provides a source of healthcare and economic benefit to the community. Moreover, it contributes to the country's development. The issue of the unlawful exploitation of traditional medicine goes against this theory as it hinders the owners from being able to make a profit from their works.

2.3 Person-hood theory

This theory propounds that in order for one to achieve proper development they must possess control over the resources in their environment. This control takes the form of property rights. [31]

The person-hood justification for property emphasizes the extent to which property is personal as opposed to fungible: the justification is strongest where an object or idea is closely intertwined with an individual's personal identity and weakest where the 'thing' is valued by the individual at its market worth.[32]

Hegel, the main propounder of this theory observes, "an author's personality or spirit cannot be free unless he owns the work he created".[33] This theory intermingles the spirit of the author to his work and enforces him with rights which remain with him even if ownership no longer does. In copyright law, this is referred to as moral rights. This allows the author of the work to have some control over his expression as it allows him to seek redress if his work is mutilated.

This theory can be used as a justification for our study as communities with cultural knowledge have used herbal plants for generations. Over time, it has formed part of their culture and evidently become a symbol of identity for the communities. Therefore, they are entitled to property rights over their traditional knowledge. Furthermore, the misappropriation of this knowledge leads to

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[30] *Mazer v Stein*, 1954, United States Supreme Court.
[31] Radin, M, 'Property and Personhood', 34 *Stanford Law Review*, 1982, 957-1015
[32] Menel P, 'Intellectual Property: General Theories', *Berkeley Centre for Law and Technology,*1999,158.
[33] Hegel G, 'Philosophy of Right', Oxford University. Press, 1952.

the mutilation and destruction of the moral rights of these communities and should be compensated for it.[34]

Conclusion

From the above theories, we can establish that the protection of traditional knowledge for indigenous communities is necessary in the attainment of justice. This protection not only guarantees the protection of the interests of the community but the interests of society in general.

[34] Article 6, *Berne Convention for the Protection of Literary and Artistic Works*, 9 September 1886, UNTS Volume Number, 828 (p.221).

3 CHAPTER THREE: NATIONAL AND INTERNATIONAL LEGISLATIVE FRAMEWORK FOR THE PROTECTION OF TRADITIONAL MEDICINAL KNOWLEDGE.

3.1 Introduction

The following chapter shall delve into the legislative framework governing the protection of traditional knowledge with particular interest in medical knowledge. This study will analyze the laws from both a national and international perspective with the view of understanding the relevant laws in its entirety.

However, before the analysis of the current legal framework, it is prudent to look at how the current need for a *sui generis* framework for traditional medical knowledge arose.

Arguments against the use of intellectual property regime governing traditional knowledge.

Many communities through the generations have passed down traditions and knowledge that they acquired from their ancestors. Such practices include the use of plants as medicine. These practices are integral to the identity, culture as well as the survival of these communities. However, Intellectual Property law fails to efficiently provide for the protection of traditional knowledge.[35]

Furthermore, as a result of the inadequacies, Intellectual Property may promote the acquisition and commercialization of traditional knowledge by people who do not belong to the community.[36] These inadequacies have led to the exploitation of traditional medicine and the like at the expense of the local communities who are not compensated for their discoveries.[37]

Another challenge intellectual property faces in the protection of traditional knowledge is the fact that IP protection such as patents and copyright have a limited duration of protection. Copyright

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[35] Oseitutu J 'A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' 12, *Marquette Intellectual Property Law Review* 1 , 2012.
[36] Oseitutu J 'A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' 12, *Marquette Intellectual Property Law Review* 1 , 2012.
[37] Nunez A, 'Intellectual Property and the protection of traditional knowledge, genetic resources and folklore: the Peruvian experience.12, *'Max Planck Yearbook of United Nations Law*, 2008, 500.

protection is limited to 50 years after the death of the author[38] while patents are protected for a period of 20 years after which it becomes prior art.[39] On the other hand, traditional knowledge requires indefinite protection due to the fact that it is transgenerational in nature and is a symbol of identity for the community.[40]

Conventional IPR protections are put in place to protect the individual rights of the owner. This would prove difficult in the case of traditional knowledge such as traditional medicine as they are shared amongst the community. It would thus be unjust to give one member of the community the right over another. Furthermore, traditional knowledge is developed over several generations over a period of time and practised in numerous countries. Therefore, it does not fit the criteria of conventional IPR's which require novelty, originality and inventiveness.[41]

Even in circumstances where a communities' Traditional Knowledge may qualify for protection under IP regimes, such protection becomes impossible because the procedures for registering the rights are, in general, expensive, complicated, and time-consuming for most communities.[42]

For these reasons, many agreed that the protection of traditional knowledge is a complex matter and there was a need to establish a *sui generis* rule that would ensure the protection of the indigenous communities who discovered them. This would be possible through the introduction of access and benefit-sharing mechanisms.

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3.2 Historical development of the protection of Traditional Medical Knowledge in Kenya.

The practice of the use of traditional medicine has taken place from ancient times. All the communities had their own practices and medicinal plants which they used. This made Kenya a

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[38] Article 7(1), *Berne Convention for the Protection of Literary and Artistic Works,* May 4 1896, UNTS 828 (p.221).
[39] Article 33, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), 15 April 1994, 1869 U.N.T.S. 299
[40] Oseitutu J 'A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' 12, *Marquette Intellectual Property Law Review* 1 , 2012
[41] Kalaskar B, 'Traditional Knowledge and Sui generis law', 3, *International Journal of Scientific & Engineering Research* ,7,2012,1.
[42] Dagne T, 'Protecting Traditional Knowledge In International Intellectual Property Law: Imperatives For Protection And Choice Of Modalities', 14 *John. Marshall Review of Intellectual Property. Law,* 25, 2014, 39.

mixing pot of diverse cultures and practices carried through the generations. Illustration of this include the use of *Kithingii*, leaves used amongst the Kamba community to treat illnesses such as high fever in children. With the coming of colonialism, the practice of traditional medical knowledge was endangered as diviners and traditional healers were outlawed. This was due to the lack of understanding of African culture as they saw the practice to be barbaric and as the practice of witchcraft and magic.[43] The practice regained popularity again in modern-day as due to the low cost and ease of availability supplemented the modern healthcare system.[44]

The *National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expression* came in 2009. The aim of the policy was developing a system that contributes to the promotion and dissemination of innovations which are based on the continuing use of tradition, but also about preserving what exists as an indispensable and powerful tool for fostering continuous traditional innovation and creativity to contribute to national development.[45] The policy further laid the groundwork for the recognition and protection of traditional knowledge.

3.3 NATIONAL LEGISLATION

3.3.1 The Constitution of Kenya 2010.

The enactment of the Constitution gave rise to multiple protections for traditional medicine in Kenya. Article 11 recognizes culture as the foundation of the nation and as the cumulative civilization of the Kenyan people and nation.[46] The article further obligates the government to promote cultural expressions and to protect the intellectual property rights of the Kenyan people.[47] Moreover, the state is required to support, promote and protect the intellectual property rights of the citizens of Kenya.[48]

In line with the topic at hand, the constitution provides a duty to the government to enact legislation that will ensure that communities are compensated for the utilization of their cultural heritage.[49] Additionally, the government is required to protect the ownership of seeds and plant varieties as

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[43] Helwig, D, "Traditional African medicine". *Gale Encyclopedia of Alternative Medicine*,2005.
[44] Conserve Africa. "Africa: Overview on Medicinal Plants and Traditional Medicine". Conserve Africa,2002.
[45] Preamble, Kenya National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009. -< https://www.wipo.int/edocs/lexdocs/laws/en/ke/ke022en.pdf>- on 1 September 2019.
[46] Article 11(1), *Constitution of Kenya*,2010.
[47] Article 11(2), *Constitution of Kenya.*
[48] Article 40(5), *Constitution of Kenya*.
[49] Article 11(3), *Constitution of Kenya*.

well as their use by Kenyan communities such as in the case of traditional medicine.[50]Finally, the Constitution imposes a duty on the state to protect and enhance IP in, and indigenous knowledge of, biodiversity and genetic resources of the communities.[51] The constitution's protection for indigenous communities and culture is commendable and should be appraised for its efforts.

3.3.2 The Protection of Traditional Knowledge and Traditional Cultural Expressions Act

This Act was enacted in 2016 with the aim of providing a framework for the protection and promotion of traditional knowledge and cultural expressions. Additionally, the Act was to give effect to Articles 11, 40 and 69(1) (c) of the Constitution that have been mentioned above.[52]

Kenya has been applauded for being one of the states pioneering the protection of traditional medical knowledge by making use of the sui generis regime in Africa. This comes as a result of the debate over the need for more efficient protections for traditional knowledge other than the western established systems such as copyright, patents and trademarks.[53]

Notable features of the Act include the introduction of a digital repository whose purpose is to contain information relating to traditional knowledge and cultural expressions that have been documented and registered by county governments.[54] The Act places this function under the mandate of the county government.[55]

Another feature is the retention of moral rights for traditional medical knowledge provided for under copyright law.[56] Moral rights refer to rights that accrue to an author for the integrity and ownership of the works. These rights accrue even after one has transferred all their other rights.[57] They include, right to attribution of ownership[58], protection from false attribution of ownership of

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[50] Article 11(3)(b), *Constitution of Kenya*.
[51] Article 69(c), *Constitution of Kenya*.
[52] Preamble , *Protection of Traditional Knowledge and Cultural Expressions (Act No. 33 Of 2016)*
[53] OseiiTutu J, 'A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law', 15, *Marquette Intellectual Property Law review,*1,2011.
[54] Section 8(3), *Protection of Traditional Knowledge and Cultural Expressions.*
[55] Section 4(1), *Protection of Traditional Knowledge and Cultural Expressions.*
[56] Section 21, *Protection of Traditional Knowledge and Cultural Expressions*
[57] Harvard Law School, 'Moral rights Basics', 1998. -https://cyber.harvard.edu/property/library/moralprimer.html- on 2 September 2019.
[58] Section 21(2)(a), *Protection of Traditional Knowledge and Cultural Expressions.*

traditional knowledge[59], protection of their traditional knowledge or expression from derogatory treatment such as mutilation, alteration of the traditional knowledge or cultural expressions that is prejudicial to the honour or reputation of the traditional owners, or the integrity of the traditional knowledge or cultural expressions.[60] It should also be noted that these rights cannot be waived.[61]

The Act provides for prior informed consent. This principle refers to a situation where the owners of traditional knowledge provide complete and accurate information including the prior consent to use the traditional knowledge or cultural expression.[62] The Act provides for this in two situations; for purposes of registration by the county government[63] and before the resources knowledge is exploited.[64] This provision is part and parcel to the study of this paper as the issues surrounding the exploitation of traditional medical knowledge occur due to the lack of prior consent from the community.

The Act recognizes the misappropriation of traditional knowledge such as traditional medicine as a punishable an offence. It goes further to highlighting different situations that would amount to misappropriation such as where a person develops goods or services using unauthorized traditional knowledge, where a person makes non-customary use of traditional knowledge, where a person fails to acknowledge the source of traditional knowledge where a person distorts mutilates or does other modification or derogatory action in a way prejudicial to the cultural interests of the community among others. The punishment for these actions are imprisonment for a period not exceeding five years or a fine or both.[65]

Moreover, the Act makes provisions for mechanisms communities can use to seek redress and remedies for the misappropriation of their traditional knowledge. It allows communities to bring a civil action against offenders[66], allows them to seek civil remedies such as injunctions and damages.[67] Furthermore, it allows for disputes to be heard and determined using other mechanisms

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[59] Section 21(2)(b), *Protection of Traditional Knowledge and Cultural Expressions.*
[60] Section 21(2)(c), *Protection of Traditional Knowledge and Cultural Expressions.*
[61] Section 21(4), Protection *of Traditional Knowledge and Cultural Expressions.*
[62] Section 2, Protection *of Traditional Knowledge and Cultural Expressions.*
[63] Section 15(3), *Protection of Traditional Knowledge and Cultural Expressions.*
[64] Section 18(2), *Protection of Traditional Knowledge and Cultural Expressions.*
[65] Section 37, *Protection of Traditional Knowledge and Cultural Expressions.*
[66] Section 38, *Protection of Traditional Knowledge and Cultural Expressions*
[67] Section 39, *Protection of Traditional Knowledge and Cultural Expressions*

other than the courts such as mediation, alternative dispute resolution procedures and customary laws and practices in as long as they are consistent with the constitution.[68] The use of alternative mechanisms of dispute resolution such as mediation result in more cost effective, expeditious and flexible solutions to disputes.[69]Moreover, the use of customary law mechanisms would foster harmonious relationships between the parties. [70] Furthermore, it would cater to the specific needs of the communities such as specific religious, cultural practices or customs. [71]

The final notable provision is that which provides for benefit-sharing rights. The Act guarantees the right to fair and equitable benefit sharing for local communities who commercialize on their traditional knowledge. Furthermore, this matter should be determined by mutual agreement between the parties. [72]Furthermore, it makes accommodations for the use of non-monetary benefits as a form of consideration.[73] This provision is important in our study as this provides for legal access to traditional medical knowledge that is mutually beneficial to both parties as the agreement is made between the parties.

3.4 Regional and international legislative framework.

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

This protocol was adopted in 2010 and later amended in 2016. The protocol highlights the importance of traditional knowledge through the recognition of "the intrinsic value of traditional knowledge, traditional cultures and folklore, including their social, cultural, spiritual, economic, intellectual, scientific, ecological, agricultural, medical, technological, commercial and educational value" and that "traditional knowledge systems, traditional cultures and folklore are diverse frameworks of ongoing innovation, creativity and distinctive intellectual and creative life that benefit local and traditional communities and all humanity"[74] Though Kenya is not a signatory

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[6868] Section 40, *Protection of Traditional Knowledge and Cultural Expressions.*
[69] Kariuki M, Resolving conflicts through mediation in Kenya, Glenwood Publishers Limited, Nairobi, 2012, 3.
[70] Kariuki F, Ouma S, Ngetich R, 'Property Law', Strathmore University Press,2016,65.
[71] World Intellectual Property Organisation, 'Customary Law, Traditional Knowledge And Intellectual Property: An Outline Of The Issues'2013,23.
[72] Section 24, *Protection of Traditional Knowledge and Cultural Expressions.*
[73] Section 24(2), *Protection of Traditional Knowledge and Cultural Expressions.*
[74] Preamble, Swakopmund Protocol, 9 August 2010.

to this ARIPO agreement, the current Protection of Traditional Knowledge Act has some substantial similarity to the provisions provided by the protocol.[75]

3.4.2 Convention on Biological Diversity (CBD)

the CBD was concluded on 5th June 1992.[76] This came as a result of lengthy discussions jointly with the United Nations Environmental Program. Together they established principles to protect the environment while concurrently ensuring economic development. It emphasized on the conversation of biodiversity, sustainable use, and fair and equitable benefit sharing of the use of genetic resources.[77] Article 8(j) of the convention provides for the need for governments to respect, preserve, maintain, and promote the wider application of traditional knowledge with the approval and involvement of the relevant indigenous and local communities(ILC's). [78] The Act also reaffirms the sovereignty of a state over the biodiversity found in their territory.[79] Moreover, it incorporates provisions which provide for the encouragement, development of exchange and use of indigenous and traditional knowledge and technology in the spirit of CBD.[80]

3.4.3 Nagoya Protocol on access and benefit-sharing[81]

This protocol was adopted in 2010 and ratified by Kenya in 2014.[82] The protocol builds on provisions found in the Convention on Biodiversity. Furthermore, it supports the implementation of its provisions.

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[75] Ouma M, 'Breaking it Down: The Protection of Traditional Knowledge and Cultural Expressions Act' in 'Jahazi: Reflections on Culture, Arts & the Constitution of Kenya', 1, 2017,17. -< http://twawezacommunications.org/img/Final-Jahazi-Vol-6-Issue-1-2017-2.pdf >- on 4 September 2019.
[76] *Convention on Biodiversity*, 5 June 1992, United Nations Treaty Series, vol. 1760, p. 79.
[77] Verma S.K.& Mittal R, 'Intellectual Property Rights: A Global Vision', *Indian Law Institute*, 2006, 38.
[78] Article 8(j), *Convention on Biodiversity*, 5 June 1992, United Nations Treaty Series, vol. 1760, p. 79. See also Secretariat of the Convention on Biological Diversity, 'Traditional Knowledge',2011, 1, - https://www.cbd.int/abs/infokit/revised/web/factsheet-tk-en.pdf- on 4 September 2019.
[79] Article 3, *Convention on Biodiversity.*
[80] Roohi M, Saeema F, Majeed A, Khan A, Bhat Z, 'Legal framework on protection of traditional knowledge: a review', 8, *International Journal of Advanced Research in Science and Engineering,*1,2019.101.
[81] *The Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on biological Diversity,*2012.
[82] United Nations Development Program, '*National Individual Consultant (Technical) To Provide The Technical Backstopping For Drafting Of An Appropriate Legal Instrument On Access And Benefit Sharing For The Implementation Of The Nagoya Protocol In Keny*a',2017,1. -<

The purpose of this Protocol is to effectively implement the fair and equitable sharing of benefits arising from the utilization of genetic resources.[83] This came in response to the major criticisms the Convention on Biodiversity received for its provisions regarding access and benefit-sharing. One such criticism was directed at the protection of indigenous communities and their traditional knowledge.[84]

The protocol implemented some noteworthy provisions relating to traditional knowledge in terms of genetic resources. The protocol recognizes the rights of communities over their genetic resources.[85] The Act further states,

"*Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.''*[86]

It makes similar provisions to the Kenyan Act such as in the case of requirements of prior informed consent[87]and benefit sharing.[88]

Some of these provisions include the definition of traditional knowledge,[89] requirement that traditional knowledge should not be subject to any formality, in accordance to section 5.1 of the Protocol and it confers the owner with the exclusive right to the exploitation of the traditional knowledge.[90] It also provides for prior consent. Moreover, the provisions of the duration of

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https://www.undp.org/content/dam/kenya/docs/Procurement/2017/October2017/TOR-KEN-IC-2017-45%20-Technical%20Support%20(Legal%20Instruments%20on%20ABS%20in%20Kenya).pdf>- on 4 September 2019.

[83] Secretariat to the Convention on Biodiversity-< https://www.cbd.int/abs/about/#objective>- on 4 September 2019.

[84] Greiber T, 'An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing', International Union for Conservation of Nature(IUCN) Environmental Policy and Law Paper No. 83, 2012,18. -< https://portals.iucn.org/library/efiles/documents/EPLP-083.pdf>- on 4 September 2019.

[85] Article 5, *Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on biological Diversity,*2012.

[86] Article 5(2) *Nagoya Protocol.*

[87] Article 7, ibid.

[88] Article 5, ibid.

[89] Section 2, *Swakopmund Protocol* and *Protection of Traditional Knowledge and Cultural Expressions.*

[90] Section 5.1, *Swakopmund Protocol*, 9 August 2010. and Section 7, *Protection of Traditional Knowledge and Cultural Expressions.*

protection are similar with the exception of the circumstances provided for under Section 13 of the Protocol.[91]

3.4.4 The UN declaration on the rights of indigenous persons

This declaration was adopted in September 2007. Though not legally binding, the declaration provides a dynamic standard for the protection of the rights of indigenous people. The declaration puts emphasis on the rights of these persons to be able to maintain and foster their cultural practices and traditions so as to foster their development.

It states that measures should be put in place to provide redress for actions which results in depriving indigenous people of their integrity or their cultural values or identities.[92]

Article 24 in particular, provides for the right of indigenous persons to the use of their traditional medicine. Furthermore, it provides for the conservation of their vital medicinal plants, animals as well as minerals. The declaration makes an attempt to provide for the protection of traditional knowledge through requiring the state to put in effective measures to protect traditional knowledge, cultural expressions as well as heritage.[93] Moreover it emphasizes on the need for an international treaty for the protection of traditional knowledge.[94]

3.5 Inefficiencies in the national legal framework

According to the Traditional Knowledge and Cultural Expressions Act, an owner is defined as a "*local and traditional communities, and recognized individuals or organizations within such communities in whom the custody or protection of traditional knowledge and cultural expressions are entrusted in accordance with the customary law and practices of that community"* while a holder is defined as, *"recognized individuals or organizations within communities in whom the custody or protection of traditional knowledge and cultural expressions are entrusted in*

[91] Section 13, *Swakopmund Protocol and Protection of Traditional Knowledge and Cultural Expressions.*

[92] Article 8(2), *United Nations Declaration on the Rights of Indigenous Peoples*, 2 October 2007, A/RES/61/295.
[93] Article 31, *United Nations Declaration on the Rights of Indigenous Peoples*, 2 October 2007, A/RES/61/295.
[94] Kumar, Nithin V., 'Protection of Traditional Knowledge: International and National Initiatives and Possible Ways Ahead,' Social Science Research Network, 2012,15.

accordance with the customary law and practices of that community." The Act on providing the above definitions confuses the concept of ownership and custodianship. In this case, referring to the holder.

Under property law, ownership is defined as the quantum of rights a person has in a thing that causes people to believe that the thing belongs to him.[95] The concept of ownership accrues a sense of absoluteness such as in the possession of the property, duration one can hold the property and the power that the property should not be confiscated without prompt and just compensation.[96] Custodianship, on the other hand, refers to an agent that performs various duties on behalf of a client/owner.[97]Therefore, this implies a concept of temporary hold in terms of the rights accrued. In African property systems, ownership was vested in the community as a whole. Members of the community were only accorded access rights.[98] In relation to the Act, the use of these definitions brings about problems in relation to granting of rights and protection of traditional knowledge on both the owners and the holders. [99]

The Act also provides for the possibility of assignment with regards to traditional knowledge.[100] This poses some difficulty in reconciliation as it goes against the aspect of property as a transgenerational asset central to the African view of property. According to this view, African property relations traverse the state of affairs as perceived by the living, the past and future generations.[101]Property is thus a transgenerational asset, held for the benefit of the dead, the living and yet to be born.[102] Using this notion the rights are thus inalienable. [103]Therefore, they cannot be transferred through assignment.

The Act provides for the protection of traditional knowledge inclusive of traditional medicine from unlawful acts.[104] However, this is subject to some limitations. It is provided that *"the use of*

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[95] Kariuki F, Ouma S, Ngetich R, '*Property Law'*, 1ed, Strathmore University Press, 2016,19.
[96] Kariuki F, Ouma S, Ngetich R, '*Property Law'*, Strathmore University Press, 2016,19.
[97] Black's Law Dictionary, 2ed,-< https://thelawdictionary.org/custodian/>- on 1 October 2019.
[98] Kariuki F, Ouma S, Ngetich R, '*Property Law'*, 1ed, Strathmore University Press, 2016,20.
[99] Section 9, *Protection of Traditional Knowledge and Cultural Expressions*
[100] Section 22, *Protection of Traditional Knowledge and Cultural Expressions*
[101] Okoth Ogendo, 'The tragic African Commons', 12003, *University of Nairobi Law Journal,*2000, 5.
[102] Kariuki F, Ouma S, Ngetich R, '*Property Law'*, 1ed, Strathmore University Press, 2016,52.
[103] Mwangi C, 'Protecting traditional knowledge in Kenya through African Customary Law: an analysis of inclusive Subordination', Strathmore University, 2019,49.
[104] Section 18, *Protection of Traditional Knowledge and Cultural Expressions.*

traditional knowledge or cultural expressions shall be compatible with fair practice, the relevant community's customary laws, protocols and practices and the relevant community shall be acknowledged as the source of the traditional knowledge or cultural expressions, and such use shall not be offensive to the relevant community." [105] The Act fails to define what 'fair practice' is as well as who would be the determiner of what amounts to fair practice.

The Act introduces the use of compulsory licensing to traditional knowledge.[106] This brings about tension between the community interest v the interest of the state. The concept of compulsory licensing originates from the doctrine of compulsory acquisition by the state used in the acquisition of land. The limitation of property is the legal requirement that private property rights must bow to the superior rights of the sovereign when called upon to surrender the property for public exigencies.[107] The Act's justification of this is "where protected traditional knowledge is 'not being sufficiently exploited' by the owner or rights holder, or where the owner or holder of rights in traditional knowledge refuses to grant licenses for exploitation." The Act fails to define what amounts to sufficient exploitation which contributes to the ambiguity of the law. Furthermore, the requirement for prior consent goes against the concept of compulsory licensing as it implies lack of consent from the community.

Furthermore, the presence of this provision could lead to a situation where the interest of the state takes priority over the communities' interest which would be detrimental to the community.[108] It has been illustrated in previous chapters the centrality of traditional medical knowledge to the identification and culture of local communities. The allowance for compulsory licensing may tear into this very concept and other protections by allowing the government to bypass the community in the exploitation of traditional medical knowledge. There is a need for further debate on this issue to form clear guidelines on this matter.

Traditional Knowledge is often shared with communities in neighboring countries. However, the Act does not make sufficient provision for cross-border cooperation mechanisms to assist in

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[105] Section 19, *Protection of Traditional Knowledge and Cultural Expressions.*
[106] Section 12, *Protection of Traditional Knowledge and Cultural Expressions*
[107] Paul E, *Property rights and eminent domain'*, Transaction Publishers, London United Kingdom, 2009,185.
[108]Katiba Institute, 'AFRICA'S GIFT TO THE WORLD',2016 -< https://www.katibainstitute.org/traditional-knowledge-and-culture-expressions-act-2016/>- on 3 October 2019.

dispute resolution or management and enforcement of rights in trans boundary or foreign Traditional Knowledge. This may increase conflict between countries and within trans boundary communities and reduce regional bargaining power in enforcing community rights over Traditional Knowledge.[109]

The Swakopmund Protocol makes provisions for matters surrounding transboundary TK. The Protocol provides for the registration of traditional knowledge in order to deal with issues that may arise with regard to ownership of the same traditional knowledge existing in many communities from different countries.[110]

The Act provides for the process of obtaining prior consent before the exploitation of traditional medicine and provides for procedures for resolving disputes that arise from it making use of Alternative Dispute Resolutions Mechanisms. However, the Act fails to cater for acts of bio-piracy that took place before the law's enactment and whether provisions of the act can be used to take recourse for them.

The Swakopmund Protocol attempts to cater for this through the implementation of the following provision, "*Exploitation and dissemination of traditional knowledge prior to the entry into force of the protection under this Protocol shall comply with the provisions of section 9 relating to equitable benefit-sharing and section 10 relating to the recognition of the source, within twelve months following the entry into force of the protection, subject to equitable treatment of the rights acquired by third parties in good faith"*[111]A similar provision is given in Peru's legislative framework.

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[109] Katiba Institute, 'AFRICA'S GIFT TO THE WORLD',2016 -< https://www.katibainstitute.org/traditional-knowledge-and-culture-expressions-act-2016/>- on 3 October 2019.
[110] Vilho A, 'A Critical Analysis of the Protection of Traditional Knowledge within the Namibian Legal System', University of Capetown,2014.
[111] Section 25(4) Swakopmund Protocol.

4 CHAPTER 4: COMPARATIVE ANALYSIS OF THE PROTECTION OF TRADITIONAL MEDICINAL KNOWLEDGE IN INDIA AND PERU.

4.1 Introduction

The need for protection of traditional medicine and traditional knowledge as a whole is a fact that has been identified and acknowledged by numerous developing countries. There have been efforts made at the state level by some countries. However, many scholars still emphasize on the need for an international protection regime. There is no one size fits all mechanism for protection of traditional medicine that has been identified as of yet. Therefore, different states have adopted different regimes to protect their traditional knowledge.

The following chapter will provide a brief look into the proposals for forms of protection to get an understanding of those that exist. Additionally, a comparative analysis shall be conducted on the systems of protection for traditional medical knowledge to identify new mechanisms that Kenya can adopt to ensure the efficient protection of the rights of local communities.

The countries chosen for this analysis are India and Peru which have been chosen as case studies for the following reasons.

India was chosen as it makes use of existing intellectual property mechanisms that have been adopted to cater to traditional knowledge. Furthermore, the jurisdiction makes use of a digital library which has been in use for several years and found success. Therefore, studying the implementation of the repository will give insight as to how Kenya can implement its own repository in order to find similar success in the protection of traditional knowledge.

Peru was chosen for this case study based on its implementation of a sui generis protection system. The country was one of the first countries to introduce a law specific to traditional knowledge.[112]Therefore its advances through the years can provide insights for Kenya in its journey to protecting the rights of the local communities.

[112] United Nation Conference of Trade and Development, 'Helping Peru protect and benefit from its biodiversity', 2016. -https://unctad.org/en/pages/newsdetails.aspx?OriginalVersionID=1212- on 3 October 2019.

4.2 Proposals for protecting traditional knowledge

4.2.1 Defensive protection

This refers to mechanisms put in place to prevent intellectual property rights from being granted to unauthorized individuals.[113] There are very many forms of application of this measure. Some include;

a) Disclosure of origin

This form of protection requires the voluntary or mandatory disclosure of genetic resources or traditional knowledge being incorporated into the invention when applying for a patent.[114] The protection provides for a weak form (disclosure is voluntary) e.g Belgium makes use of this in the 1998 European Union Directive on the Legal Protection of Biotechnological Inventions[115]as well as the strong form (disclosure is mandatory) of protection as is the case in India. Where disclosure is mandatory failure to comply results in the revocation of a patent.

b) Traditional knowledge prior art databases

This involves the compilation of traditional knowledge into a database that acts as evidence of prior art by patent examiners when reviewing an application for a Patent. The most famous database to date is the Traditional Knowledge Digital Library from India which has been particularly useful in the protection of traditional medicine.[116]

c) Misappropriation regime

This mechanism gives freedom to states to come up with ways of preventing it through national law. It makes use of criminal or civil remedies such as the requirement to

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[113] -http://www.abs-canada.org/food-for-thought/legal-measures-for-protecting-traditional-knowledge-tk/- on November 2019.
[114] Access and Benefit sharing Canada, 'Legal Measures for Protecting Traditional Knowledge'-< http://www.abs-canada.org/food-for-thought/legal-measures-for-protecting-traditional-knowledge-tk/>- on November 2019.
[115] Van Overwalle, G, "Belgium goes its own way on biodiversity and patents", 5, European *Intellectual Property Review*,2002, 233
[116] Ansari M, 'Role of Traditional Knowledge Digital Library (TKDL) in Preservation and Protection of Indigenous Medicinal Knowledge of India', *Herbal Medicine in India*,2019,609-620.

compensate a community for use of their traditional knowledge or the obligation to stop using the relevant knowledge. The mechanism was proposed by Professor Carlos Correa. He proposes that such a regime should contain three elements: documentation of TK, proof of origin or materials, and prior informed consent. A document that has made use of this mechanism is the Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples.[117]

4.2.2 Positive protection

This refers to a mechanism that allows for communities to protect their traditional knowledge by granting them rights to control its use and economic exploitation. This protection can be provided through the use of existing intellectual property rights mechanisms or through the use of sui generis mechanisms. Examples of jurisdictions that have made use of this include Kenya and Peru.[118]

4.3 Comparative Analysis

4.3.1 INDIA

India is a country with a vast collection of biodiversity which has led to a plethora of traditional knowledge in the field of traditional medicine. The vast knowledge of these medicine has led to a system which is characterized by institutionally trained practitioners, a body of texts originating since ancient times, and highly developed theories to support the practices. These traditional medicine systems encompass knowledge of life, health and diseases of all living forms, not only human but also of plants and animals. Further, there exists the folk system which is characterized by practitioners who are well versed with treatments for ailments passed down through the generations.[119]

In 2000, the Traditional Knowledge Task Force did a study on 762 patents granted in the US and found that Out of these, 374(49%) patents were found to be based on traditional knowledge. A

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[117] International Centre for Trade and Sustainable Development (ICTSD), '*Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation*', 2003,38.
[118] Shrivastav V, 'Protection of Traditional Knowledge within the Existing Framework of Intellectual Property Rights: Defensive and Positive Approach', Social Science Research Network, 2014,19.
[119] -< https://shodhganga.inflibnet.ac.in/bitstream/10603/14508/9/09_chapter%203.pdf>- on November 2019.

number which increased by three-fold in the coming years.[120] One of the infamous battles India took part in the protection of traditional knowledge was in the case concerning the neem plant.

In 1992, the US patent office approved a patent for a method of creating *azadirachtin* solution. This solution was subsequently used in food crops under the name Neemix, two years later, the same person filed for another patent for the use of neem as an anti-fungal product with the European patent office. This was later challenged by India and the Patent subsequently revoked in 2000.[121]

India ratified the Convention on Biodiversity in 1992. As a result of this, the countries of the South Asian region are required to adopt and implement certain measures to develop national strategies, plans or programmes for the sustainable use of biodiversity in their own countries.[122] India's response to this was the Biodiversity Act of 2002. It is described as "*an Act to provide for the conservation of biological diversity, sustainable use of its components and fair and equitable benefit sharing arising out of the use of biological resources, knowledge and for matters connected*.."[123].The Act serves as the regulator of traditional knowledge. This was in part a response to cases of bio privacy that were evident in its past as well as the introduction of the TRIPS agreement. The Act introduced the National Biodiversity Authority (NBA).The mandate of this body is to manage requests concerning access rights to biological resources by foreigners, control the transfer of research conducted in India and determine the sharing of benefits that would arise as a result of its commercialisation.[124]

The Act further prescribes some special provisions for the protection of traditional knowledge. One of which is restricting the transfer of any research for monetary consideration or otherwise to

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[120] -< https://shodhganga.inflibnet.ac.in/bitstream/10603/14508/9/09_chapter%203.pdf>- on November 2019.
[121] Balasubramiam 'Traditional Knowledge And Patent Issues: An Overview Of Turmeric, Basmati, Neem Cases', 2017,- <http://www.mondaq.com/india/x/586384/Patent/Traditional+Knowledge+And+Patent+Issues+An+Overview+Of+Turmeric+Basmati+Neem+Cases>- on November 2019.
[122] Kariyawasam K, 'Access to Biological Resources and Benefit-Sharing: Exploring a Regional Mechanism to Implement the Convention on Biological Diversity (CBD) in SAARC Countries',29, *European Intellectual Property Review*, 8, 2007, 328.
[123] *Biological Diversity Act*, 2002 (Act No. 18 of 2003)
[124] Section 8, *Biological Diversity Act*, 2002 (Act No. 18 of 2003)

people without the approval of the Authority.[125]These provisions are put in place to ensure efficient and transparent access to biodiversity through written agreements.[126]

In 2001, India introduced the Plant Varieties and Farmers' Rights Act. This Act was enacted to fulfil its obligation under TRIPS to protect its plant varieties. It was useful in protecting traditional knowledge as it recognized the rights of farmers to a portion of the interest obtained from the commercialisation of their plant varieties. This was achieved through granting of patents and sui generis intellectual property rights.[127]

Also, in line with the TRIPS Agreement, India amended its Patent laws through the Patent Amendment Act 2002.

The changes made progression in the protection of traditional knowledge. This includes the restriction placed on the definition of a patent. The law states, "any invention *which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' will not be an invention*."[128]

Secondly, the law included a provision for the opposition of "a complete patent specification of an invention which was publicly known or publicly used in India before the priority date of that claim."[129] It is said that the reason for all these provisions was to defy the challenges that arose due to misappropriation of traditional knowledge which already existed in the public domain as a result of its existence in Indian communities from time immemorial.[130]

Another provision which has contributed greatly to the protection of India's traditional medical knowledge is the establishment of the Traditional Knowledge Digital Library. This repository acts as a database that is able to preempt and prevent the grant of a patent in foreign jurisdictions using the concept of prior art.[131] The idea came about in the midst of India's efforts to revoke a patent

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[125] Article 3&4, *Biological Diversity Act*, 2002 (Act No. 18 of 2003)
[126] Venkataraman K, 'Intellectual Property Rights, Traditional Knowledge and Biodiversity of India', 13, *Journal of Intellectual Property Rights*, 2008
[127] Venkataraman K, 'Intellectual Property Rights, Traditional Knowledge and Biodiversity of India', 13, *Journal of Intellectual Property Rights*, 2008,332.
[128] Section 3(p), *Patents (Amendment) Act*, 2002 (Act no, 38 of 2002)
[129] Section 25(3)(d), *Patents (Amendment) Act*, 2002 (Act no, 38 of 2002)
[130] Venkataraman K, 'Intellectual Property Rights, Traditional Knowledge and Biodiversity of India', 13, *Journal of Intellectual Property Rights*, 2008,334.
[131] Suvapan J, 'Traditional Knowledge Digital Library: What could we Learn from India?', 2016,91.

granted by the US patent and trademark office for Turmeric's healing properties.[132] At the time of its implementation, much of the knowledge on medicine were only in traditional languages such as Sanskrit, Hindi, Arabic, Urdu and Tamil making it difficult to read and protect.[133]

Currently, the repository has been able to overcome this problem through the introduction of information technology tools and a novel Traditional Knowledge Resource Classification System (TKRC). With this, the repository has been able to transcribe and translate all the information into the international languages of commerce as well as in line with International Patent Classification (IPC) format to allow for international protection.[134] The repository even went as far as including descriptions of yoga practices due to the increase in trials to patent them internationally.

In 2006, the Government of India agreed to collaborate with International Patent Offices by giving them access to the Digital library. For this, they made use of Non-Disclosure agreements. Parties to this agreement included the European Patent Office, US patent Office, Japan Patent Office, UK patent office and Canadian Intellectual Patent Office.[135] Since 2009, with the help of TKDL, 5,100 patent applications relating to Indian medicinal knowledge at various Patent Offices accessible to TKDL have been identified[136]

The introduction of the Digital Library has had a great impact beyond the revocation of patents. It has aided in the preservation of knowledge as the information contained in the library aids in the dissemination, use and management of this knowledge for the future generation, the mechanism can be used as a tool to fuel future innovation as it acts as a medium between traditional medical knowledge and modern science. This will be essential in the research to form new drugs.[137]

This innovative step taken by the country has been appraised by the international community for its innovation in the protection of traditional knowledge. Kenya has since also introduced a digital

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[132] World Intellectual Property Organisation, 'Protecting Indian Traditional Knowledge from Biopiracy',2011. - https://www.wipo.int/export/sites/www/meetings/en/2011/wipo_tkdl_del_11/pdf/tkdl_gupta.pdf- on December 2019.
[133] World Intellectual Property Organisation, 'Protecting Indian Traditional Knowledge from Biopiracy',2011
[134] Suvapan J, 'Traditional Knowledge Digital Library: What could we Learn from India?'2016,94
[135] Sen S, Chakraborty R, 'Traditional Knowledge Digital Library: a distinctive approach to protect and promote Indian indigenous medicinal treasure', 106, *Current Science,*10,2014,1342.
[136] PCT minimum documentation: Indian traditional knowledge digital Library, see Annex I Summary of the Indian Traditional Knowledge Digital Library, 3.
[137] Hirwade, M. and Hirwade, A., "Traditional knowledge protection: An Indian prospective," 246

repository into its national legislation for the protection of traditional knowledge. However, it has yet to be implemented. If properly implemented by the government similar success should be expected as in the case of India.

4.3.2 PERU

The protection of traditional knowledge in Peru came as a result of its initiatives of protecting new plant varieties. An innovative protection was brought about by Decision 345 on a Common Regime for the Protection of the Rights of Breeders of New Plant Varieties 1994.[138] However, problems arose as the Act solely provided for new plant varieties that were established as a result of science. This greatly excluded plant varieties that were native to the Andes and Amazonian indigenous communities. These two communities were also important to the biodiversity in Peru as they contributed to its conservation as well as the development of new species. The debate on this issue sparked a whole new wave of policy aimed at the protection of not only native crops that would be excluded but traditional knowledge as a whole.[139]

Peru further amended its Industrial Property Act to recognize the need for a *sui generis* regime for the protection of the knowledge of local communities. Moreover, it included requirements for the registration of traditional knowledge. This legislation was the first intellectual property law that explicitly mentioned traditional Knowledge. Soon thereafter, the Law for the Conservation and Sustainable Use of Biodiversity (1997) was enacted. It established that knowledge and practices of indigenous communities formed part of their culture. Furthermore, it called for the development of procedures and tools that would manage their use and dissemination.[140]

In 2002, The protection of Traditional Knowledge Act came to force. It was the first law protecting traditional knowledge in the world.

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[138] Article 4, Decision 345 on a Common Regime for the Protection of the Rights of Breeders of New Plant Varieties (1994),

[139]Rosell M, 'Access to Genetic Resources: A Critical Approach to Decision 391, "Common Regime on Access to Genetic Resources,"' 6, *Review of European Community & International Environmental Law* ,3, 1997.

[140] Ruiz P, 'The Protection of traditional knowledge in Peru', 3, *Washington University Global Studies Law Review*,2004,755.

Article 1 provided for the right of indigenous communities to determine how they would make use of their traditional knowledge and how they structure their dealings with third parties.[141] Furthermore, it guarantees indigenous peoples the right to set their own priorities for the process of development, as it affects their lives, beliefs, institutions, and spiritual well-being. It also grants them the right to exercise control over their economic, social, and cultural development.[142]

The law is very centered on the concept of communal ownership. The rights provided for traditional knowledge are inalienable. Therefore, they cannot be transferred. They can only be licensed.[143] Further, the sharing of benefits from the commercialization of traditional medicine is done at the communal level and not at the individual level. The Act does not cater to individual rights as those are protected by traditional customs.[144]

Peru has established the National Biopiracy Commission, which is chaired by INDECOPI whose functions are to identify, analyse and deal with cases of biopiracy of traditional knowledge of indigenous Peruvians. As of 2017, the commission had resolved 15 cases of biopiracy of Peruvian native plants.[145]

The Act provides an exception to the protection for knowledge present in the public domain.[146]It recognizes the fact that some of the information present in the public domain may have not been consented to by the communities. Therefore, it set a precedent by providing that if traditional knowledge has entered into the public domain within the last twenty years then a portion of the sales from the goods developed with that resource shall be incorporated into a fund that will be

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[141] Article 2.1, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources,* 2002, (Law no. 27811)
[142] Clark S, Lapena I, Ruiz M, 'The Protection of Traditional Knowledge in Peru: A Comparative Perspective', 3, *Washington University Global Studies Law Review*,3,2004,755. see also Article 7.1 *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources,* 2002, (Law no. 27811)
[143] Romero T, 'Sui generis systems for the protection of traditional knowledge', Revista colombiana de derecho internacional,2005,327.
[144]Clark S, Lapena I, Ruiz M, 'The Protection of Traditional Knowledge in Peru: A Comparative Perspective', 3, *Washington University Global Studies Law Review*,3,2004.
[145] Moeller IP Advisors, 'Peru Is Leader Against Biopiracy',12 December 2016. -< http://www.mondaq.com/Peru/x/552022/Patent/Peru+is+leader+against+biopiracy>- on 14 December 2019.
[146] WIPO, '*Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge And Folklore: Overview Of Activities And Outcomes Of The Intergovernmental Committee*',2003.

used in development projects for the indigenous communities.[147]However, they could not prevent its use.

The Act makes provision for prior informed consent through the use of an application indicating the request for authorization, information regarding it use , risks that would be associated with the activity to be conducted as well as its value.[148] The system is different as it makes use of representative organisations chosen by the people to represent their interests. However, in the authorization for consent, the representative organisation upon receiving the application is required to inform a majority of the community to discuss the application.[149] This is particularly important especially when it comes to culturally sensitive factors such as religion for the participation of the community to be included.

In terms of benefit-sharing, the Act makes specific provisions for the license agreement to include a benefit-sharing condition. Furthermore, it establishes two rates:

1. Initial direct payment for the utilization of the traditional knowledge as well as five percent of the net sales, before taxes, of goods developed directly or indirectly from the Traditional Knowledge.[150]
2. At least ten per cent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples. [151] However, the Act leaves it up to the community to decide upon a higher rate.

The Peruvian Act provides for the use of two protection tools: registers and licenses.

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[147] Article 37, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources,* 2002, (Law no. 27811)
[148] Article 27, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources,* 2002.
[149] Article 6, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources,* 2002.
[150] Clark S, Lapena I, Ruiz M, 'The Protection of Traditional Knowledge in Peru: A Comparative Perspective', 3, *Washington University Global Studies Law Review*,3,2004,755.
[151] Article 8, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.* See also Clark S, Lapena I, Ruiz M, 'The Protection of Traditional Knowledge in Peru: A Comparative Perspective', 3, *Washington University Global Studies Law Review*,3,2004,755.

In terms of registers, the Peruvian model makes use of 3 different registers with varying levels of confidentiality. This allows it to adapt to the nature of Traditional Knowledge. The registers include Public National Register, a Confidential National Register, and Local Registers.[152]

i. The Public National Register is developed and managed by the National Institute for the Defense of Competition and Intellectual Property (INDECOPI). All information regarding data to do with traditional knowledge found in the public domain is transcribed and stored here to aid Patent offices around the world in the novelty and inventive step analysis of patent applications.[153]
ii. The confidential register was a reform introduced by the ILC's during the preliminary phases of the law. The purpose of this register is to systematize any traditional knowledge that the community may want to keep confidential. This information will be inaccessible to third parties in line with their wishes.[154]
iii. Local registers are initiatives by the indigenous communities for the storage of their traditional knowledge which is controlled in line with their practices and customs.[155] Similar registers have been implemented in some states in India.

The use of registers serve as a defensive mechanism by preserving data through its compilation and storage, regulate the dissemination of the traditional knowledge by giving control to the indigenous communities and blocks the unlawful grant of patents without due recognition to communities by providing patent offices to access to information on traditional knowledge in the jurisdiction

Licenses have been discussed above in part with prior consent. The Act provides for a criterion of information that should be present the agreement. Licenses are obtained through INDECOPI after which the information remains confidential.[156] The exception to this rule is if the third party obtains

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[152] Article15, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*
[153] Article 17, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources*
[154] Article 18, , *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*
[155] Article 24, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*
[156] Article 28. *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*

consent from the community to discuss which should also be in a written agreement. Use of licenses is mandatory and subject to certain minimum requirements. These requirements include: "Must be in written form, must be in Spanish and any other native language, should be renewable for at least one year and not more than three years"[157], must identify the parties involved and have a description of the traditional knowledge to be used, condition guaranteeing the equitable distribution of benefits from the commercialization of the traditional knowledge.[158]

Uniquely, the Peruvian Act provides for a fund for the development of indigenous communities. The purpose of this fund is to protect and improve the living conditions of the indigenous communities as a whole. This shall be done through the financing of development projects which have been chosen by the communities based on their needs. Sources of finance to sustain this fund include; "State budget, international technical cooperation, donations, the percentage of economic benefits from information in the public domain as well as those set aside for the fund in accordance with article 8, the fines imposed by law."[159]

The Peruvian Act imposes a duty on INDECOPI to contribute to the conservation of the environment. It does so by requiring the body to seek further information either by the request of the party or *ex-officio* on cases it considers will result in an impact to the environment of the indigenous communities. Furthermore, INDECOPI is required to reject the registration of a contract if such a risk is detected the parties have been notified to put in place measures to avoid them but fail to do so to the extent required by the Environmental regulatory body.

From the above Comparative analysis, we can see some commonalities between the two systems.

Both systems provide for a register for the compilation and storage of descriptions of traditional knowledge which has had great success in the prevention of granting unlawful patents

[157] Article 26, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*
[158] Article 7, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*
[159] Article 41, *Law Introducing A Protection Regime for The Collective Knowledge Of Indigenous Peoples Derived From Biological Resources.*

internationally without the recognition and just compensation of the local communities which discovered them.

Secondly, both systems have made provisions for access and benefit-sharing mechanisms as well as the requirement of prior informed consent from the communities involved before proceeding with the exploitation of the resources.

The right to grant licenses to third parties has been seen in both jurisdictions with requirements for the above provisions. Furthermore, the provisions for mandatory licensing through the relevant authorities has been a common aspect as well. Such provisions are important to ensure efficient and transparent protection of traditional knowledge.

It is clear that both jurisdictions have adopted defensive forms of protection for traditional knowledge. These measures integrates the patent system to access and use of traditional knowledge and biological resources. All this is to achieve the objective of the Convention on Biodiversity on benefit sharing.

5. CHAPTER FIVE: CONCLUSION AND RECOMMENDATION.

SUMMARY

The protection of traditional medical knowledge has been a highly debated topic over the last couple of years. This is with good reason as traditional knowledge as a whole is central to the proper functioning of society. It has played a significant role in areas such as trade, healthcare, food security, sustainable development, culture and the environment.[160] The growth of the use of traditional knowledge has led to cases of misappropriation of the knowledge by third parties to the detriment of the local communities who discovered them. This has especially been evident in third world countries. In recent times, these third world countries have made strides in trying to reacquire their lost knowledge through legal protections such as intellectual property rights such as Copyrights, Patents, trademarks etc. However, the sole use of intellectual property rights has failed to adequately protect indigenous communities' rights due to their structure as highlighted in Chapter three of this study. As a result, a new wave of policy has emerged to fill the gaps left by the western protections through the use of sui generis regimes as well as modified intellectual property regimes as highlighted in chapter 4 of this study.

The study aimed to identify the discuss the legal framework surrounding the protection of Traditional medical knowledge in Kenya with the purpose of identifying any gaps that could hinder the efficient protection of traditional medical knowledge and encourage the practice of biopiracy. Furthermore, it aimed to identify changes that can be made both to the law as well as the implementation of the law to improve the prevent the exploitation of traditional knowledge through the analysis of other regimes in place around the world. This was achieved through the comparative analysis conducted in chapter 4.

RECOMMENDATIONS

It is for this reason that I make the following recommendations

[160] Salgotra R, Zargar S, Sharma M, 'Traditional Knowledge: A Therapeutic Potential in the Scenario of Climate Change for Sustainable Development', 61, Palgrave Macmillan; Society for International Development, 2018,1.

1. There is need for clarity on some of the definitions and wordings used in the Act. This prevents any misunderstanding when implementing the law and the avoidance of loopholes
2. There is need to delete the provision of the Act that concerns compulsory licensing by the cabinet secretary as it goes against the right of the local community to control the use of their traditional knowledge.
3. There is a lack of clarity as to whether the provisions of the Act can be used retrospectively to matters of exploitation before its enactment. This is a practice that has been noted in Peru.
4. In the implementation of the digital repository in Kenya, there is need to ensure that the information collected is made accessible to the international patent offices as evidence of prior art for its success as defensive protection as noted in India and Peru.
5. The digital repository should include different categories such as what is in Peru to allow for the confidentiality of traditional knowledge which the communities do not wish to share.
6. Kenya should implement the use of representative organisations as used in Peru. This would make decision making my the communities easier to manage and would solve the issue of the impractical consolidation of prior consent from all members of the community who might be located all over the country.
7. Kenya should consider setting up a fund to cater for the preservation of indigenous communities as is seen in Peru.
8. Kenya should impose a duty in its laws on the county government to ensure that agreements entered into with foreign nationals are in line with environmental laws and obligations. Furthermore, activities that have environmental risks should not be permitted by the government.
9. There is a need to provide education and training to members of indigenous communities to inform them of their rights and the recourse they have in case of situations of exploitations by third parties. neighbouring is essential to the success of the Act.

CONCLUSION

Kenya should be applauded for its bold steps in establishing a *sui generis* law for traditional knowledge, the Protection of Traditional Knowledge and Cultural Expressions Act. The law has established protections that suit the dynamic nature of traditional knowledge however, there exist some inconsistencies in the framing of the law that allows for the continual misappropriation of traditional medicine.

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