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PROTECTION OF TRADITIONAL KNOWLEDGE UNDER INTERNATIONAL AND ETHIOPIAN LAW WITH A PARTICULAR REFERENCE TO TRADITIONAL MEDICAL KNOWLEDGE: CURRENT TRENDS, PROSPECTS AND CHALLENGES

A Thesis Submitted in Partial Fulfillment of the Requirements of LL.M. Degree in Public International Law

BY: Gizachew Girma

Student Number: GSR/3204/01

Prepared under the Supervision of Dr. Fikremarkos Merso

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Plagiarism Declaration

I GIZACHEW GIRMA DEGEFU, do hereby declare that the thesis *'PROTECTION OF TRADITIONAL KNOWLEDGE UNDER INTERNATIONAL AND ETHIOPIAN LAW WITH PARTICULAR REFERENCE TO TRADITIONAL MEDICAL KNOWLEDGE: CURRENT TRENDS, PROSPECTS AND CHALLENGES'* is my original work and that it has not been submitted for any degree or examination in any other university. Whenever other sources are used or quoted, they have been duly acknowledged.

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Dr. Fikremarkos Merso	……	…….
Imiru Tamirat	……	…….
Abebe Abebayehu	……	…….

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Acronyms

ABS- Access and Benefit Sharing (follow same rules

ABS-WG – CBD ad hoc working group on Access and Benefit Sharing

Art. - Article

CBD- Convention on Biological Diversity

COP- Conference of the Parties

CRBL- Biodiversity law of the Republic of Costa Rica

DACA- The Drug Administration and Control Authority

Doc. Document

EHNRI- Ethiopian Health and Nutrition Research Institute

EIPO- Ethiopia Intellectual Property Office

ENTMPSA- The Ethiopian National Traditional Medicine Preparation and Study Association

EU- European Union

FAO- Food and Agriculture Organization

FTTD- Formulas on Traditional Thai Drug

IBCR- Institute of Biodiversity conservation and Research

ILO- International Labor Organization

IP- Intellectual Property

IPC- International Patent Classification

IPR- Intellectual Property Right

NGO- Non-Governmental Organization

P. - Page

Parag. - Paragraph

PCT- Patent Cooperation Treaty

PIC- Prior Informed Consent

PLT- Patent Law Treaty

PP. - Pages

Sec.- Section

TCMPD- Traditional Chinese Medicine Patents Database

TK- Traditional Knowledge

TKDL- Traditional Knowledge Digital Library

TM- Traditional Medicine

TMK- Traditional Medicinal Knowledge

TMP- Traditional Medicinal Practitioners

TRIPS- WTO Agreement on Trade Related Intellectual Property Rights

TTIA- Thai Traditional Medicinal Intelligence Act

TTM-IPRs -Traditional Thai Medicinal Intellectual Property Rights

TTTM- Texts on Traditional Thai Medicines

UN- United Nations

UNEP- United Nations Environmental Programme

UNESCO- United Nations Educational, Scientific and Cultural Organization

US- United States of America

WG-8(j)- CBD Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions

WHO- World Health Organization

WIPO- World Intellectual Property Organization

WIPO-IGC- WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

WTO- World Trade Organization

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Abstract

This thesis, reviews and analyzes different international agreements and initiatives, and examines the legal environment and policies of Ethiopia relevant to the protection of Traditional Knowledge (TK) with a particular reference to Traditional Medical Knowledge (TMK). It also assesses inherent and possible problems of existing and potential modalities of protection considering the experiences of some countries, so as to suggest different option that could be applied to protect TK/TMK.

Analysis of different instruments and initiatives reveals the fact that there is no single system of legal protection of TK/TMK adopted and proposed both at the national and international level. At the international level little concrete progress has been achieved to protect TK. Multiple practical and theoretical reasons are identified as challenges to reach effective international legal regime for the protection of TK/TMK. The principal factors, inter alia, include difficulty to endorse 'one size fits all' legal machinery to the great diversity of TK systems and variation of interests among different countries and groups.

In Ethiopia little work has been performed yet to protect TK/TMK and little information is available on TMK system of Ethiopia. There is no comprehensive legal regime to effectively protect TMK in Ethiopia. The only national legal regime to protect TK/TMK- Access and Benefit Sharing (ABS) legislation- fails to address individually held TMK, and this thesis calls for the amendment of ABS law to recognize and protect individually held TKs in consultation with relevant stakeholders. The thesis argues that Intellectual Property Rights (IPRs) and/or similar exclusive property rights are not appropriate tools to protect TMK of Ethiopia as it stands now. And it suggests that employing a bundle of mechanisms i.e. benefit sharing, confidential documentation and introduction of mandatory disclosure requirement- is the best alternative to achieve the objectives Ethiopia sought from protecting TMK.

Key words: Traditional Knowledge, Traditional Medical Knowledge, Intellectual Property, Access and Benefit Sharing, Sui generis, Documentation

CHAPTER ONE

1. INTRODUCTION

1.1. Background

Due to the increasing importance of knowledge in the economic affairs of nation-states across the world, protection of knowledge has become a major point of interest in recent years. As Drahos has put it, '*Information is becoming 'the prime resource' in modern economic life'*.[1] The centrality of knowledge in today's global economic system has given rise to what has been termed the "*knowledge economy*" in which the weight of global economic activity is shifting towards knowledge-oriented products and services.[2] The prime position of knowledge has made it a centre of various economic, social and political claims and conflicts between different stakeholders at the local, national and international levels.[3]

Human communities have always generated, refined and passed on knowledge from generation to generation. Such 'Traditional knowledge'[4] (TK) has been used for centuries by indigenous and local communities under local laws, customs and traditions; and it is often an important part of their cultural identities.[5] TK has played, and still plays, an important role in vital areas such as food security, the development of agriculture and medical treatment.

Recently, Western science has become more interested in TK and realized that TK may help to find useful solutions to current problems, sometimes in combination with modern scientific and technological knowledge. Especially, Traditional medical knowledge (TMK) - a subset and one kind of TK- has become a primary point of research that attracts researchers and

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[1] Peter Drahos, *the Universality of Intellectual Property Rights: Origins and Development,* Paper presented at Traditional Knowledge and Cultural Expressions Panel Discussion on Intellectual Property and Human Rights, Geneva 2 (1999) available at http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf [accessed on May 26, 2010]

[2] Michael P. Ryan, *Knowledge-Economy Elites, the International Law of Intellectual Property and Trade, and Economic Development*, 10 CARDOZO J. INT'L & COMP. L. 271- 304 (2002)

[3] Alex Tawanda Magaisa, *Knowledge and Power: Law, Politics and Socio-cultural Perspectives on the Protection of Traditional Medical Knowledge Systems in Zimbabwe*, in 3 NEW DIRECTIONS IN COPY RIGHT LAW 56, 56 (Fiona Macmillan ed., 2006)

[4] Several terms are used by different legislations, organizations and scholars to refer to Traditional Knowledge. These, *inter alia*, includes indigenous knowledge, (systems and practices)', 'community knowledge', 'intangible cultural heritage' and 'indigenous cultural and intellectual property' to name a few.

[5] Carlos M Correa, *Traditional Knowledge and Intellectual Property: Issues and options surrounding the protection of traditional knowledge*; a Discussion Paper 3 (2001) available at http://www.quno.org [accessed on May 26, 2010]

pharmaceutical companies in the search for commercial drugs to deal with various ailments so that it saves considerable amount of time and money.[6]

Despite the growing recognition of TK as a valuable source of knowledge, historically it has generally been regarded under Western intellectual property laws as information in the "*public domain*", freely available for use by anybody.[7] Differing circumstances- including modern technology, wealth and power render developed countries better than developing countries to exploit these freely available public good.[8] Moreover, in some cases, TK mainly from developing countries, have been commercially appropriated under intellectual property rights (IPRs) by researchers and commercial enterprises from developed countries, without any compensation/benefit go to the knowledge's creators or possessors.

This scenario alerts developing countries to voice their concerns for the need to protect TK at the international level. This concern also pushes most of the developing countries- including Ethiopia- to endorse legislations and/or amend the existing laws at the national level, so as to protect misappropriation of TK through IPRs and to share the benefits accrued from using TK. Similarly, the situation derives the issue of protection of TK, to emerge as a new agenda in many international fora and treaty negotiations, including in the Convention on Biological Diversity[9] [CBD], World Intellectual Property Office[10] [WIPO], World Trade Organization[11] [WTO] and World Health Organization[12] [WHO].

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[6] Magaisa, *supra* note 3

[7] Correa, *supra* note 5

[8] Anupam Chandert & Madhavi Sunder, *The Romance of the Public Domain*, 92 CAL. L. REV. 1331, 1336 (2004)

[9] The Convention on Biological Diversity (CBD) is an international legally-binding treaty, opened for signature at the Earth Summit in Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993; with three main goals: conservation of biodiversity; sustainable use of biodiversity; fair and equitable sharing of the benefits arising from the use of genetic resources. To date, it has 193 Parties. The Secretariat of the Convention on Biological Diversity (SCBD) is based in Montreal, Canada. UN Convention on Biological Diversity, June 5, 1992, reprinted in 31 ILM 822 [here in after CBD] Information on the CBD is available at http://www.cbd.int/ [accessed on May 26, 2010]

[10] The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations. It was established by the WIPO Convention in 1967 with a mandate from its Member States to promote the protection of IP throughout the world through cooperation among states and in collaboration with other international organizations. Its headquarters are in Geneva, Switzerland. Since 1999, WIPO involved in the protection of TK establishing an open ended Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC- GRTKF). Information on WIPO's work can be accessed from http://www.wipo.int/tk/en/tk/ [accessed on May 26, 2010]

1.2. Statement of the Problem

The issue of TK protection has been dealt with in some national laws, and debates have also taken place in different international fora, where numerous studies and proposals have been made. However, several proposals have failed to setout clearly the rational for its protection. Any system of protection is an instrument for achieving certain objectives. Therefore, a fundamental question, before considering how TMK may be protected, is to define why it should be. It should be after identification of the policy objectives sought to be achieved that the modalities of protection need to be discussed.

IPRs are seen as one possible means to protect TK/TMK. There are both ardent proponents and critics of extending IPRs to TK/TMK. Those who advocate the application of IPRs to TK/TMK find that there are many examples of TK/TMK that are or could be protected by the existing IP system, or by modifying certain aspects of the current forms of IPRs protection. Those who are reluctant or opposed to the idea of applying existing IPRs or creating a new form of IPRs to protect TMK base their arguments on both practical reasons and principles, namely the essential incompatibility between the concepts of Western IPRs and the nature of practices and cultures of local and indigenous communities. Different alternatives to IPRs for dealing with TK/TMK or some components thereof have been proposed and even adopted. In order to appreciate appropriate legal machineries that would effectively protect TK/TMK and achieve its policy objective, there should be a discussion and analysis of the various modalities of protection (within and outside the IPR system), proposed and adopted in some international organizations and some national jurisdictions, and test the validity of the claimed problems. Consequently, it could be possible to settle the confusion of 'as to what extent do these legal machineries are convenient to protect TK/TMK' so that identify problems inherent to different protection modalities and possible options to tackle them.

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[11] WTO is an international organization, established by the Marrakesh Agreement in 1994 and enters in to force in 1993. It administers bulk of international agreements that intends to liberalize international trade. Information about WTO can be accessed from its website http://www.wto.org [accessed on May 26, 2010]

[12] The World Health Organization (WHO), is the directing and coordinating authority on international health within the United Nations' system. WHO's Constitution came into force on 7 April 1948, and to date it has 193 countries and 193 countries and two associate members. Members meet every year at the World Health Assembly in Geneva to set policy for the Organization, approve the Organization's budget, and every five years, to appoint the Director-General. Their work is supported by the 34-member Executive Board, which is elected by the Health Assembly. More information is available online at http://www.who.int/ [accessed on May 26, 2010]

Ethiopia has laws and policies directly or indirectly concerned with protection and promotion of TMK or otherwise affect it negatively or positively. Thus, it is essential to examine the existing policy and legal environment related to the subject to see what has been provided and what elements are missing to create an enabling environment for the protection of TMK. Similarly, it is also necessary to scrutinize current efforts that are being made to protect, promote and preserve TMK in Ethiopia. Accordingly, the scope, form and nature of protection granted to TMK; whether they are transformed in to practice and implementation problems encountered; and the gaps that need to be filled, needs to be ascertained.

Since there are various objectives that are usually sought from protecting TK and in particular TMK, it is essential to clearly define the objectives and rational of protection of TMK with in the Ethiopian context. It is also necessary to identify the interest of Ethiopia from international protection of TMK so that the country can wisely take part in the international negotiations. The feasibility of potential candidates for the protection of TMK- including IPRs- to achieve the identified policy priorities have to be tested in line with the current situation of Ethiopia and available TMK. After all identification of the problems that needs to be rectified is crucial, to suggest the best available solutions.

1.3. Objective of the study

1.3.1. General Objective

The general objective of the study is to explore issues related with the protection of traditional knowledge with a particular reference to traditional medical knowledge at the international level and under the Ethiopian legal system.

1.3.2. Specific Objectives

- Discuss and clarify the term TK generally, and TMK specifically.
- Describing different theoretical and legal issues on why TK, in particular TMK should be protected.
- Discuss the discourse on the nature and scope of protection to be granted to TK/TMK and explore different initiatives that have been made, at the international level; discuss international protection provided for TK/TMK.

- Pinpoint the interests of Ethiopia that have to be secured from the international and national protection of TMK.

- Discuss the legal regime of Ethiopian on the protection of TMK; ascertain the nature and scope of protection granted to TMK; explore other possible ways to protect and test their desirability.

- Identify the challenges of protecting TMK in Ethiopia and suggest the best available solution to alleviate the problem.

1.4. Research Questions

This research will strive to seek answer to the following main research questions:

- What is traditional knowledge/ traditional medical knowledge?

- What has been done to protect TK at the international and Ethiopian level? What protection is granted to TMK at the international level and with in the Ethiopian legal system? What gaps need to be filled? What objective is sought to be achieved through protection of TMK? What are the problems for the protection of TMK?

- Can the existing IPR regime be used to protect TMK? To what extent do existing IPRs already afford protection? In what way? Are they effective and desirable? What problems are faced?

- What possible other options are available for the preservation, protection and promotion of TMK?

1.5. Significance of the Study

The study is hoped to have important contributions. First, it will serve as an input to further research in the area. Second, the findings and recommendations of the study will serve as a stepping stone for further review of Ethiopian legal and institutional regime on the way that fulfills its obligation under international law and that can secure the interest of the country in general and holders of TMK in particular. Third, the finding of the study will serve as a guideline to Ethiopian delegates negotiating in different international fora for the protection of TK, by indicating the best interests of Ethiopia.

1.6. Research Methodology

The methodology that has been used in this study is mainly a desktop study which includes an analysis of the existing literatures, policies and laws including relevant primary and secondary sources. Information has been gathered from books, internet, articles and journals. Assessment of studies conducted in different parts of Ethiopia regarding the subject at hand and interview those individuals who participate in data gathering was made in order to explore the attitude of Traditional Medical Practitioners (TMPs) as to their knowledge and their needs and expectation regarding the protection of TMK. Though there is no traditional healers association functioning today, it has been tried to detect the position of the former Ethiopian National Traditional Medicine Preparation and Study Association (ENTMPSA)- legally dissolved before two years- from decision passed and letters sent by the association at the time it is operational. Furthermore, three traditional healers (Two from Addis Ababa and one from Laga Tafo) who were members and key participants of the former association and now struggling to rekindle it are also interviewed. Other seven experts and government officials from different government institutions are also interviewed.

1.7. Limitation of the Study

This study by the very nature of its subject matter- Medical Knowledge- requires knowledge of technical terms related to medical science, biology, botanical science, taxonomy and other fields of natural science. Though I am indulgent to familiarize my self to these concepts, it is hardly possible to claim that lack of knowledge in the area concerned will not pose a problem in the collection of data and the way I express the concepts in the study.

Financial problems, time constraint, inconsistent connection of the internet and unavailability of materials- especially books- were the major problems encountered in conducting the study. In addition, while TMPs association is dissolved, to have an interview with TMPs was difficult task for me due to lack of cooperation of some TMPs. Considering, these difficulties, it was hardly possible to claim the study is comprehensive.

1.8. Scope of the Study

TK is diverse in substance and content and encompasses a wide range of subject matter that concerns all aspects of life- (food, health, housing, communications, culture, religion etc.) and

the environment (relations between biodiversity and ecological factors, identification criteria of biodiversity elements, etc.). Thus, the term TK is wide enough to include tangible resources such as genetic resources and expressions of TK also named traditional cultural expressions (TCE) in both tangible (material)- e.g. paintings and musical instruments- and intangible forms- e.g. tales, dances and songs. Nevertheless, in this thesis the term TK is not used to connote tangible TK and TCEs; rather it is used to refer only TK in *stricto sensu*- the knowledge itself.

TK in *stricto sensu* also covers a wide range of subject matters. These categories of TK, *inter alia*, include agricultural, scientific, technical, ecological, medicinal and biodiversity related knowledge, to name a few. Though these categories of TK have common characteristics to share, their content is perfectly different that would in turn have an implication to the forms and modalities of protection. As one can easily capture from this fact, it would be an elusive task to deal with all TK and its protection. Therefore, this thesis will focus on TMK although the umbrella notion of TK, of which TMK is a sub-set, will be referred and hence discussed constantly.

1.9. Organization of the Thesis

The main body of the thesis was organized in the fashion that would give clear and coherent understanding of the general message of the study, dividing it in to five chapters. In order to avoid redundancy of discussion, citations were used to make cross reference to other relevant sections. The first chapter is designed to draw on the reader, the general picture of the study. And it gives an insight about the general background, the principal issues addressed, objectives sought to be achieved, significance, methodologies used, limitations and scope of the study. After that since it is necessary to understand first the meaning, importance and scope of the subject matter of the study (TK and TMK) -this is described in Chapter two.

The third chapter is the discussion on issues, problems and strategies on the protection of TK/TMK at the international level. The starting point for any discussion about protection should then be to clarify why there is a need to protect it, and what can be achieved. Thus at the forefront of this chapter the main arguments for protection are considered. Subsequent to that different modalities of protection proposed and adopted are discussed. The topic entitled IP and TK/TMK, after brief examination of the major objections rose to IP protection of

TK/TMK, explore and test the potential and difficulties in applying different IPRs in particular patents, trade secrets, trademarks and geographical indications to protect TK/TMK. Similarly, with in the matrix of IP system defensive protection of TK from misappropriation is briefed. The discussion on the international benefit sharing regime out of the utilization of TK is also made, along with the discussion on progresses made in the CBD and initiatives undertaken by WIPO. The other strategy proposed, debated in different international fora and even adopted in some countries is *sui generis* system of Protecting TK/TMK, which is discussed in the same chapter together with highlighting experience of four countries and initiatives of four international organizations. At the end of this chapter, different conflicting interests in protection of TMK are briefed.

Chapter four specifically discusses protection of TMK in Ethiopia. The chapter opened by description of TMK system of Ethiopia and its role. In the next subsection expectations of TMK holders and the objectives Ethiopia needs to secure from protection of TMK are ascertained, in a in a manner that aims at furthering an understanding on the what should be the direction of protection. It is essential to examine the current policy, legal and institutional mechanisms and other practical efforts made relevant to the protection of TMK, to see what has been done and provided and what is missing and what shall be done. Looking these, therefore, the thesis in this chapter systematically tries to unpack the problems inherent in the current system and test the feasibility of other possible modalities of TMK protection, in light with their efficacy in achieving the stated objectives. After all, it shows alternative approaches that could be employed to protect TMK in Ethiopia.

Finally, the main findings- but not summary- of the study are stipulated and by way of recommendation indication of the potential solutions for the major problems was made, under the heading conclusions and recommendations.

CHAPTER TWO

2. INTRODUCTION TO TRADITIONAL KNOWLEDGE (TK) AND TRADITIONAL MEDICAL KNOWLEDGE (TMK)

2.1. Traditional Knowledge (TK)

The term Traditional Knowledge, [TK] has become popular in modern international discourse, and acquired a wide usage in many academic disciplines spanning from law to sociology, anthropology and natural sciences. Since it encompasses a wide range of subject matter, it arises as an issue in fora relating to food and agriculture, biodiversity and the environment, biotechnology innovation and regulation, human rights, cultural policies and trade and economic development to name a few. The working concept of TK in each forum tend to be shaped by the policy framework of that forum, leading to a decentralized and disintegrated set of approaches, in which the issues are subjected to differing policy considerations, cultural and ethical environments, analytical tools and legal concepts.[13]

2.1.1. What is TK?

There is no universally agreed and legally precise definition to the term TK as it can be defined in deferent ways. According to WIPO, there is no need for a complete and authoritative definition of TK in order to develop a legal system for its protection.[14] What an operational definition of TK requires is the designation of its essential elements, and not a singular definition.[15] Accordingly, WIPO uses the term TK in broad and inclusive manner to refer:

> *[T]radition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations*

[13] WIPO, *Traditional Knowledge – Operational Terms And Definitions*, Document prepared by the Secretariat to the third Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore [here in after IGC], at Para. 15, WIPO Doc. WIPO/GRTKF/IC/3/9 (May 20, 2002)

[14] WIPO, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – An Overview,* Document prepared by the Secretariat to the First Session of the IGC, at Para. 65, WIPO Doc. WIPO/GRTKF/IC/1/3(March 16, 2001)

[15] *Id.*

> *resulting from intellectual activity in the industrial, scientific, literary or artistic fields.*[16]

This definition gives due emphasis to the '*Intellectual Activity'* that reflects WIPO's involvement in the protection of TK in so far as it could be considered as Intellectual Property [IP]. Hence, this is said to be an objective approach to the scope and meaning of TK that determines not what TK is but what is protectable in TK by IP System. For that reason it excludes categories of TK not resulting from intellectual activity.

> *[…]Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge; "expressions of folklore" in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of TK would be items not resulting from intellectual activity in the industrial, scientific, literary or artistic fields, such as human remains, languages in general and other similar elements of heritage in the broad sense.*[17]

Many international, regional and national laws and instruments have taken WIPO's general and objective approach to the working concept of TK. But for legislative techniques, the scope of TK is narrowed by designating other elements in addition to WIPO's criterion. Consequently, some of them define TK, with reference to the nature of the persons or communities which develop or hold TK,[18] a particular subject matter,[19] or specifying the

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[16] WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders:* Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), at Para. 25, (2001) [here in after WIPO FFM Report]

[17] *Id.*

[18] Convention on Biological Diversity, June 5, 1992, reprinted in 31 ILM 822 [here in after CBD] Art. 8(j) ". . . knowledge, innovations and practices *of indigenous and local communities* embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity*"* (emphasis added)

[19] African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Genetic Resources adopted by OAU, 2000 Part II – Definitions; "Community Knowledge or indigenous knowledge is the accumulated knowledge *that is vital for conservation and*

conditions to be fulfilled in order to obtain legal protection[20]. Similarly, Ethiopian law on Access to Genetic Resources and Community Knowledge, and Community Rights [Ethiopian ABS law], defines protectable TK, for the purpose of the law, as '[…] *knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and use of genetic resources'.*[21]

2.1.2. Nature of TK

As mentioned in the previous section, there is no widely accepted definition of TK that could be applied to all the diverse forms of TK. Furthermore, most laws and instruments do not seek to define TK in one singular and exhaustive definition. Instead, to make clear the scope of TK, illustrative or descriptive characterizations are chosen. Thus, the criteria of the characterizations are noteworthy in order to appreciate TK more. Though there is a diversity of cultures and local knowledge systems that pose difficulty to make generalization, certain characteristics are common to many TK systems.

Creation of TK is an incremental and collective process generally perceived as pertaining to a particular people or territory, but it does not follow that TK is not the product of individuals and held by the same.[22] Depending on the customary laws and principles applicable to particular situations, nothing stands in the way of recognizing an individual creation as a genuine piece of TK.[23] TK hold by individuals is common in the field of Traditional Medicine where traditional healers kept their knowledge confidential. For instance, the biodiversity law of Costa Rica recognizes all forms of TK be they individual or collective.[24]

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sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities" (emphasis added)

[20] The Biodiversity Act of Bhutan Royal Government, Bhutan Ministry of Agriculture, Water Sheep Year 2003, Art. 3 "Traditional Knowledge includes any knowledge that generally fulfills *one or more* of the following *conditions*: i) Is or has been transmitted from generation to generation. ii) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan. iii) Is collectively originated and held" (emphasis added)

[21] Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, Proclamation No. 482/2006, Art. 2(14)

[22] Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office*: *A Road Under Construction*, *in* BIODIVERSITY AND THE LAW INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE, 241, 243 (Charles R. McManis ed., 2007)

[23] *Id*.

[24] Biodiversity law of the Republic of Costa Rica, Decree No. 7788 adopted by the Legislative Assembly of the Republic of Costa Rica in April 23rd of 1998, Art. 7(2)

Only ideas that are created in a traditional and informal way constitute TK.[25] In other words, unlike formalized, scientific and industrialized research that integrates formal processes of invention and innovation; TK cannot be generated in laboratories or other places of systematic research and development. Rather, it is developed as a response to the needs imposed by the physical and cultural environments that dictate the lifestyles of traditional communities and indigenous peoples; and generated through an incremental, 'trial and error' method developed according to the rules, protocols and customs of a certain community. [26]

The working concept of TK puts a particular emphasis on the fact that TK is '*tradition based'*. That does not mean, however, that TK is old. The adjective 'traditional' does not necessarily relate to the nature of the knowledge but qualifies the informal way and the traditional context it was acquired and used, and the way it is transmitted from one generation to the next either orally or in codified form.[27] Instead, TK is in a constant state of change building upon the experience of earlier generations and adapting to the new environmental and socio-economic changes and challenges of the present.[28] Thus the body of TK will never be static; rather it is dynamic in its shape and substance.

TK covers a wide range of subject matter not confined to one state of art.[29] Moreover, TK systems are holistic, in the sense that both spiritual and practical elements have the same purpose of integrating the community with its environment.[30] TK is also part of the holistic world views of traditional communities that is inseparable from their ways of life, cultural values, spiritual beliefs, customary legal systems.[31] Consequently, TK is associated in an

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[25] *Id.*
[26] *Id.*
[27] WIPO FFM Report, *supra* note 16, at 25 *'"Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment.*'
[28] Michael J. Balick, *Traditional Knowledge: Lessons from the Past, Lessons for the Future*, *in* BIODIVERSITY AND THE LAW INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE, 280, 280 (Charles R. McManis ed., 2007); *Id.*
[29] WIPO, The Protection of Traditional Knowledge: Revised Objectives and Principles, Document prepared by the Secretariat to the Sixteenth Session of the IGC, ANNEX Art. 3/2, WIPO Doc. WIPO/GRTKF/IC/16/5 (March 22, 2010)
[30] WIPO, Intellectual Property and Traditional Knowledge Booklet No. 2, WIPO Publication No. 920(E), at 1 [here in after WIPO Publication No. 920(E)] available at http://www.wipo.int/tk/en/tk/index.html [accessed on May 20, 2010]
[31] *Id.*

indissoluble manner with the identity of the community and serves as means of cultural identification.[32]

2.1.3. Traditional vs. Scientific knowledge

Knowledge systems can be classified into two broad categories which have their own validity- traditional and scientific/western knowledge. One way of understanding TK, therefore, is to make a comparison with its counterpart scientific knowledge. There is a vast body of literature on such comparison between Western science and TK systems, identifying various characteristics and opposing views.[33]

Western science is said to be objective, quantitative, positivist, materialist and based on an academic and literate transmission, in contrast to TK, which is mainly subjective, qualitative, spiritual that does not make distinctions between empirical and sacred and often passed on orally from one generation to the next by the elders.[34] Western science is experimental which isolates its object of study from their vital context, whereas TK is contextual that depends on particular local conditions.[35] Moreover, TK systems adopt more holistic approach considering that a world is made up of constantly forming multidimensional cycles in which all elements are part of an entangled and complex web of interactions, as opposed to western science which separate observation in to different disciplines and interpret reality on the basis of a linear conception of cause and effect.[36]

While it certainly must be acknowledged that there are numerous differences between the two knowledge systems, Vermeylen argues that the polarities between, TK and scientific knowledge are too simplistic and politically constructed, not the accurate description of the

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[32] WIPO/GRTKF/IC/3/9, *supra* note 13, at 33

[33] Agrawal has classified the distinctions that are made in the mainstream literature about traditional knowledge into three categories: substantive grounds which concern the nature of reality; methodological/epistemological grounds which concerns the ways to arrive at knowledge of reality; and contextual grounds which concern intimate knowledge of the environment that are not obtained merely by coming to know the Laws of nature. *For detail discussion See:* Arun Agrawal, *Dismantling the divide between Indigenous and Scientific Knowledge*, 26 DEVELOPMENT & CHANGE 413-439 (1995)

[34] Graham Dutfield, *TRIPS Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 241 (2001); Iaccarino Maurizio, *Science and Culture*, 4EMBO Rep. 220–223(2003) Fulvio Mazzocchi, *Western Science And Traditional Knowledge: Despite Their Variations, Different Forms Of Knowledge Can Learn From Each Other*; 7(5) *EMBO Rep.* 463–466(2006)

[35] Mazzocchi, *supra* note 34

[36] *Id*.; Dutfield, *supra* note 34, at 241

reality.[37] Of course, since knowledge systems are dynamic entities that change through contact, exchange and communication; there exists a considerable interface between the two knowledge systems.[38] Therefore, it should be recognized that difference should not lead to dichotomizing opposites, but can be part of everyday life. From this brief overview of the dissimilarities, we can gain an understanding of the overly distorting risk of trying to analyze and validate TK by using external (scientific) criteria.

2.1.4. Benefits of TK

Today, there is a growing appreciation of the wider significance of TK.[39] TK has been, and continues to be, important for both humans and the environment. It has been estimated that 85 *percent* of the world poor rely on biological resources and its related TK as the mainstay of their existence and livelihood.[40] Thus, besides its cultural and sacred value, it supplies much of the world's population with the principal means to fulfill their basic needs, and forms the basis for decisions and strategies in many practical aspects, including interpretation of meteorological phenomena, medical treatment, water management, production of clothing, navigation, agriculture, husbandry, hunting, fishing and biological classification systems.[41]

This knowledge is valuable not only to those who depend on it in their daily lives, but to modern industry and agriculture as well. The contribution of TK to the modern industry is enormous ranging from small scale to big business industries. These include: arts and crafts; tourism; biotechnology; advertising; film; academic/research; and music industries to name a few.[42] Many widely used products, such as plant-based medicines, health products and cosmetics, are derived from TK (for better discussion on the value of Traditional Medical

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[37] Saskia A. F. Vermeylen, Between Law and Lore: The Tragedy of Traditional Knowledge 37 (2007) (Unpublished PhD Dissertation submitted to Centre for Environmental Strategy University of Surrey)

[38] Graham Dutfield, *Protecting Traditional Knowledge And Folklore: A Review Of Progress In Diplomacy And Policy Formulation;* UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development 13 (2002) available at http://ictsd.org/downloads/2008/06/cs_dutfield.pdf [accessed on May 26, 2010]

[39] The wider significance of TK can be exemplified by the fact that it arises in international discussions on a host of issues – food and agriculture; biological diversity, desertification and the environment; human rights, especially the rights of indigenous peoples; cultural diversity; and trade and economic development.

[40] Rhys Manley, *Developmental Perspectives of the TRIPS and Traditional Knowledge Debate*, 3 MACQUARIE J. INT'L & COMP. ENVTL. L. 113, 113 (2006)

[41] Mazzocchi, *supra* note 34

[42] T. Janke, *Our Culture, Our Future*, Report prepared for the Australian Institute of Aboriginal and Torres Strait Islander Studies and the Aboriginal and Torres Strait Islander Commission, 13-16 (1999) available at http://www.frankellawyers.com.au/media/report/culture.pdf [Accessed on May 26, 2010]

Knowledge/TMK, *see* section 2.2.2). TK's contribution to the world seed varieties is essential whereby the present agricultural products are the result of the informal selection, production, hybridization and diffusion of seeds.[43] Furthermore, TK is the origin of a great variety of artistic expressions, including musical works and handicrafts to which it makes an immense contribution to the industries related to artistic works. For instance, the steady increasing number of artistic works incorporating cultural songs and dances in line with their rising recognition and popularity can best attest the role of TK in the music industry of Ethiopia.

TK can also make a significant contribution to sustainable development.[44] As discussed earlier, TK offers holistic approach that recognizes symbiotic character of humans and nature so that its holders live in harmony with nature. The presence of the vast majority of the world biological resource in the global south- the place where most indigenous and local communities situated- proves the significance of practicing TK to enhance and promote biodiversity.[45] Thus, beyond its obvious benefit to the people who rely on TK, it provides humanity as a whole with rich biodiversity so that prevents climate change and aid in maintaining healthy ecosystems. The skills and techniques of those who hold this knowledge has also a potential values for the management of natural resources by providing valuable information to the environmental policies to natural disaster preparedness and response at local and global level.[46] For instance in 2004, indigenous communities had escaped the tsunami's wrath off the coast of Indonesia by using their TK that kills more than 250, 000 lives.[47] Of course, this is not to romanticize TK and to assert the ideal of the '*noble savage*'[48]. Not all indigenous people have lived or are living in peace and harmony with nature; history has shown many cultures disappear after they had exhausted the environment's ability to

[43] Correa, *supra* note 5, at 3

44 *For Detailed Discussion See-* UNESCO, *Combating Desertification Traditional Knowledge And Modern Technology for the Sustainable Management of Dry land Ecosystems*, Proceedings of the International Workshop Elista, Russian Federation June 23–27, 2004, at 1- 62, UNESCO–MAB Dry lands Series No. 4, (2005) Available at http://unesdoc.unesco.org/images/0013/001391/139182e.pdf [accessed on May 20, 2010]

[45] Available at CBDs website http://www.cbd.int/traditional/intro.shtml [Accessed on June 25, 2010]

[46] Elias D. et al., *The Knowledge That Saved the Sea Gypsies*, 3(2) *A World of Science 20,* 20–23(2005)

[47] *See generally: Id.*

[48] The 'Noble Savage' is an idealized concept of uncivilized man, who symbolizes the innate goodness of one not exposed to the corrupting influences of civilization, and a dominant theme in the Romantic writings of the 18th and 19th. Available at http://www.britannica.com/EBchecked/topic/416988/noble-savage [Accessed on August 2nd , 2010]

sustain their population.[49] However, many existing traditional practices are ecologically healthy, and we cannot simply dismiss them as primitive and unscientific belief systems.[50]

2.1.5. Types and Categories of TK

Efforts have been made to classify the various types of TK. Gervais loosely divided TK in to four categories Vis. 1) sacred intangible 2) sacred tangible 3) secular tangible; and 4) secular intangible.[51] Similarly, WIPO recognized that TK includes both tangible and intangible components.[52] Tangible component of TK refers to genetic resources[53] and tangible cultural properties[54]. However, WIPO currently uses the term TK as comprising two main (and to some extent distinct categories). These are: TK in *stricto sensu*- the knowledge itself- and expressions of TK, whereby the two categories form TK in *lato sensu*.[55] Expressions of TK also named traditional cultural expressions (TCE) includes: verbal expressions (tales, poetry, riddles), musical expressions (songs and instrumental music), expressions by action or performances (dances, plays and artistic forms or rituals), whether or not reduced to a material form, and tangible expressions (productions of art, such as drawings, paintings, carvings), musical instruments and architectural forms.[56] Though TK in *stricto sensu* is not limited to any specific domain of art, it can be organized in to three basic subsets i.e. 1) Traditional

[49] Mazzocchi, *supra* note 34
[50] *Id.*
[51] Daniel J. Geravais, *Spiritual but Not Intellectual? The Protection of Sacred Intangible Traditional Knowledge*, 11 CARDOZO J. INT'L & COMP. L 467, 474 (2003-2004)
[52] WIPO FFM Report, *supra* note 16, at 86
[53] Genetic resources encompass pharmaceutical as well as natural products and crop genetic resources. *See* Stephen B. Brush, *The Demise of 'Common Heritage' and Protection for Traditional Agricultural Knowledge*, in BIODIVERSITY AND THE LAW INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE, 297, 304 (Charles R. McManis ed., 2007)
[54] Liu compiled tangible cultural property components of TK to include 1) immovable cultural properties including sacred and historically significant sites and burial grounds 2) movable cultural properties such as artifacts; and, 3) human remains and tissues. *See*: Yinliang Liu, *Justification of Subject-Matter for Legal Protection of Traditional Knowledge*, 29(11) EUROP. INTEL'L. PROP. REV. 456, 457 (2007)
[55] WIPO, *Consolidated Survey of Intellectual Property Protection of Traditional Knowledge*, Document prepared by the Secretariat to the fifth Session of the IGC, at Paras. 6-10, WIPO Doc. WIPO/GRTKF/IC/5/7 (April 4, 2003)
[56] UNESCO/WIPO Model Provision For National Laws On The Protection Of Expressions Of Folklore Against Illicit Exploitation And Other Prejudicial Action, done in 1982, Sec. II

Agricultural Knowledge, 2) Traditional Ecological Knowledge, and 3) Traditional Medical Knowledge.[57]

2.2. Traditional Medical Knowledge (TMK)

2.2.1. What is TMK?

Because Traditional Medical Knowledge [TMK] is a subset and important part of TK, there are basic features it shares with other categories of TK, discussed in the previous sections. Like any other form of TK, influenced by factors such as history, personal attitudes, philosophy and cultural conditions, TMK vary greatly from country to country and from region to region. [58] TMK may be codified, regulated, taught openly and practiced widely and systematically; conversely, it may be highly secretive, mystical and extremely localized, with knowledge of its practices passed on orally.[59] TMK may involve the use of products (including plants or parts of plants, animals or parts of animals, and minerals) or/and, processes (including methods, procedures or ceremonies), in which these two aspects practiced alone or in combination.[60] In addition, as noted elsewhere TK is dynamic; like TK, TMK can be both ancient and cotemporary/new.[61]

Given the diverse and broad range characteristics, elements and viewpoints of TMK systems it is difficult to assign precise definition or description of TMK. WHO, while recognizes this difficulty underlines the need to have a working definition that should be comprehensive and inclusive.[62] It thus concludes that Traditional Medicines [TM]:

> *[Include] diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies*

[57] WIPO/GRTKF/IC/16/5, *supra* note 29, Art. 3(2)
[58] WHO, WHO Traditional Medicine Strategy 2002-2005, at 7, WHO Doc. WHO/EDM/TRM/2002.1 (2002) [here in after, WHO TM strategy]
[59] *Id*.
[60] Richard Wilder, *Protection of Traditional Medicine*, CMH Working Paper Series, Paper No. WG 4: 4, 10 (2001)
[61] Yinliang Liu, IPR *Protection for New Traditional Knowledge: With A Case Study of Traditional Chinese Medicine,* 25(4) EUROP. INTEL'L. PROP. REV. 194, 195 (2003)
[62] WHO TM Strategy, *supra* note 58, at 7

manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness.[63]

This definition goes beyond Ethiopian ABS law and many other instruments discussed before, which bound TK to knowledge associated with the use of biological resources. Unlike these laws, depending on the therapies involved, TM therapies can be categorized as, medication therapies- if they use herbal medicines, animal parts and/or minerals- or, non-medication therapies- if carried out primarily without using medication.[64] TMK is concerned not only with the curing of diseases but also with the protection and promotion of human physical, spiritual, social, mental and material wellbeing.[65]

Whereas there is wide diversity at a practical level, a basic philosophical underpinning of most of such knowledge systems is their acceptance of a shared worldview which is an inherent relationship and sharing of key elements between the outside universe and a living being.[66] In addition, there are also other common dimensions of ecological centeredness, focus on non-material or non-physical dimension and a comprehensive approach to health, keeping in mind physical, mental, social, emotional, spiritual, ecological factors in wellbeing.[67]

As noted elsewhere, the diversity of cultures, beliefs and local situations of people of the world, suggest the variety systems of TMK. Needless to say, the practitioners of TMK are also different based on the customs of the society and depending on the degree of expertise in which the administration of the medicine requires. Of course, there is also considerable individual variation in interest and knowledge of TM. Notwithstanding this variation, there is a shared fund of knowledge among ordinary people for handling every day problems of their

[63] *Id*.
[64] *Id*.
[65] Kebede Deribe, et al., *A Historical Overview of Traditional Medicine Practices and Policy in Ethiopia*, 20(2) ETHIOP. J. HEALTH DEV. 127, 128 (2006)
[66] Unnikrishnan Payyappallimana, *Role of Traditional Medicine in Primary Health Care: An Overview of Perspectives and Challenges*, 58 (2010) available at http://kamome.lib.ynu.ac.jp/dspace/bitstream/10131/6917/1/4Payyappallimana.pdf [Accessed on July 13, 2010]
[67] *Id*.

lives.[68] Accordingly, some TM are widely used and known by almost all members of a given community. For instance, any person in Ethiopia can tell you the medicinal use of *Dama Kese* [scientifically known as *Glinus lotoides*] which is the old tradition of self care in the home and the plant mostly grown in every home garden. Conversely, some of the knowledge is only known by some practitioners or even by a single individual specialized in a specific- e.g. bone setting- or cluster of related diseases. In such cases the knowledge often kept secret and passed orally- but not necessarily true- from father/mother to favorite child or is acquired by some spiritual/customary procedures.[69]

Therefore, as often asserted TMK is not only collectively held; rather a single individual or selected group of persons also held this knowledge. One thing to be noted here is that TMK holders, as discussed above, are not necessarily confined to defined geographical location because such knowledge cross-cuts communities as well as territorial boundaries.[70] So it is possible to have more than one communities or individuals in different regions, who are holders of the same TMK.

2.2.2. Benefits of TMK

Since time of immemorial, TM has been used for human and livestock health care in every region of the world. Although modern medicine is introduced centuries ago, significant number of the people still uses TM, especially in the developing countries. For instance, according to WHO, in developing countries, up to 80 *percent* of the population depend mainly on TM to meet their health care needs.[71] There are a number of reasons for such broad usage in these countries.

First, in this region where majority of the population is poor, TM is the only affordable treatment in which access to modern health care services is limited by economic reasons. To

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[68] Sujatha V., *Pluralism in Indian Medicine: Medical Lore as a Genere of Medical Knowledge*, 41(2) CONTRIBUTIONS TO INDIAN SOCIOLOGY (n.s.) 169, 180 (2002)

[69] Kebede, et al. (2006) *supra* note 65, at 128

[70] *Hagenia abyssinica* (in Ethiopian locally called Kosso) is a well-known treatment for tapeworms in humans and livestock, in Ethiopia and elsewhere, including Tanzania and Kenya. *See*. JAY MCGOWN, OUT OF AFRICA: MYSTERIES OF ACCESS AND BENEFIT SHARING 7 (2006)

[71] In Ethiopia 90 *percent* of the population use traditional medicine for primary health care and is considered to be the highest as compared to other developing countries. *See generally:* WHO Fact Sheet No. 134, (December 2008) Available at http://www.who.int/mediacentre/factsheets/fs134/en/index.html [Accessed on July 26, 2010]

be clear, modern medicines and health care services are generally expensive, while conversely TMs are considerably cheaper and even some times needs no payment at all.[72] Second, even if affordable modern medicine is beyond the reach of the rural inhabitants, due to the fact that majority of modern health care centers are located in major cities and towns while a vast majority of the population - a figure that approaches 75 *percent* or more-[73] of the third world reside in the countryside. Third, in many developing countries the number of TM practitioners starkly out number modern medicine practitioners[74] set aside the self help and house hold TM employed without the need to have practitioners in which everyone is expertise. Furthermore, TM is not only widely used in the rural areas of developing countries; it is also highly popular in urban areas because it is firmly embedded within wider cultural and religious belief systems.[75]

TM is also popularly used and plays a significant role in the health care needs of developed countries where the demand for TM as alternative/complementary medicine has grown in recent years,[76] no matter how the safety, quality and efficacy of TM is questioned by modern science. The increased usage of TM in these countries indicates that factors other than traditional belief, cost and accessibility are at work. It is believed that the wide usage of TM

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[72] WHO TM Strategy, *supra* note 58, at 13

[73] Gustavo Anríquez & Libor Stloukal, *Rural Population Change in Developing Countries: Lessons for Policymaking*, ESA Working Paper No. 08-09 at 2 (November 2008)
The total percentage of rural population in Ethiopia is increases from the average that estimated to be 84 *percent* according to the 2007 census. *See generally*: Federal Democratic Republic of Ethiopia population Census Commission, *Summary and Statistical Report of the 2007 Population and Housing Census*, 19 (2008)

[74] In sub Saharan Africa, WHO estimates that traditional practitioners outnumber modern medicine practitioners by 100 to 1. WHO TM Strategy, *supra* note 58, at 12

[75] Besides its role in healing, for instance, traditional Ethiopian medicine is also associated with a number of other beliefs which is believed to be helpful in prevent the evil eye, overcoming demons, defeating human enemies, obtaining long life, clear eye sight, a good memory, as well as a large family and a faithful wife. In addition, there is also the belief that supernatural forces are involved in causing disease as well as in their treatment.

[76] Zhang summarize the government and non-government reports of developed countries populations that used complementary and alternative medicine at least once. i.e. Germany – 90 *percent*, France – 49 *percent*, Canada – 70 *percent*, Australia – 48 *percent*, the United States – 42 *percent*, and Belgium – 31 *percent*. *See*: Xiaorui Zhang, *Traditional Medicine: Its Importance and Protection; In* PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS 1, 3 (Sophia T. & Promila K. eds., 2004)

in these countries is fueled by concerns about the diverse effects of modern chemical drugs, a desire for more personalized health care and greater public access to health information.[77]

The value of TM for the world economy shall not be underestimated, since the global market for TM and medicines incorporating TMK is growing and it becomes an object of international trade. Though reliable data on total expenditure on TM is scarce, estimates have been made for sales of herbal products world wide and in selected market. WHO has estimated that the world market for herbal medicines based on TK has reached US$ 60 billion, with national growth rates between 5 *percent* to 15 *percent*.[78] As many developed countries are showing growing interest in TM; for developing countries, TMK also potentially forms the basis for an important domestic industry and for export that is an important source of earning for the national economy.[79]

Above all, TMK has been used as a lead to development of new modern drugs, so that saves the time and investment of pharmaceutical companies.[80] Now a day, due to the promises of TM, TMK has become a primary point of research in the search for commercial drugs to deal with various ailments including currently non-curable diseases like HIV/AIDS.[81]

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[77] WHO, '*Traditional Medicine –Growing Needs and Potential',* WHO Policy Perspectives on Medicines No. 2, 1(May 2002)

[78] WHO TM Strategy, *supra* note 58, at 12

[79] For example, it has been estimated that sales of traditional pharmaceutical products in China in 1996 consisted of 43.8 *percent* of the total medicine sales in China. 11,360 commercial enterprises and 35,339 business units have been set up. The output of traditional Chinese pharmaceutical products annually is 199 thousand tons, 5.8 billion dollars can be earned by the export of traditional Chinese pharmaceutical products. Liu Bao-Yan, *The Role of Traditional Medicines and Practices in the National Health Care System,* Paper presented at WIPO Asian Regional Seminar on Intellectual Property Issues in the Field of Traditional Medicine, New Delhi, India, 7-9 (October 1998) *as cited in* Wilder, *supra* note 60, at 10

[80] Data's suggest that 50 *percent* of the medicines used today originally were used by traditional and local people other than westerners. *See*: SUTTON, M.Q. & ANDERSON, E. N., INTRODUCTION TO CULTURAL ECOLOGY 105 (2004) *as cited in* Marion Panizzon, *Traditional Knowledge and Geographical Indications: Foundations, Interests and Negotiating Positions,* NCCR Trade Regulation, Swiss National Center of Competence and Research Working Paper No. 2005/01, 9 (2006)

[81] Mpazi S. & Robin R., *Protecting Traditional Knowledge and Traditional Medicines of Indigenous Peoples through Intellectual Property Rights: Issues, Challenges and Strategies*, 12 INT'L J. ON MINORITY & GROUP RTS. 1, 8 (2005)

CHAPTER THREE

3. PROTECTION OF TK/TMK AT THE INTERNATIONAL LEVEL: ISSUES, PROGRESSES AND CHALLENGES

3.1. Objectives of Protection

TK has received increasing attention on the international agenda over the past decades, and several proposals have been made with in and outside IPRs systems to protect it. It is fact that any system of protection is an instrument for achieving certain objectives. Therefore, before considering the modalities of protection, it is worth mentioning to primarily define why it should be protected. Following will be a brief overview of some of the main policy objectives sought to be achieved by protection of TK.

There are several policy objectives that are perceived in both international instruments and discussions and domestic legal regimes for the protection of TK including TMK. Many of the specific objectives perused from protection in different fora and legal documents can be grouped into the following broad categories.

I. Recognition

Despite the enormous economic and cultural values of TK, lack of respect and recognition for TK and its holders in the era of modernization and globalisation is witnessed. [*See:* Sec. 2.1.5. & 2.2.2.] Thus, one of the objectives of protection is to recognize the intrinsic and instrumental value of TK and to promote respect for TK systems.

II. Preservation

One of the great concerns of TK holders is the loss of traditional life styles and TK that is reported to be lost at an alarming rate.[82] Researches revealed that younger members of traditional communities are reluctant to carry forward traditional practices that may demise an entire tradition and knowledge system.[83] In countries where TK is being rapidly lost, preservation of TK may be of key importance so that it could be able to transfer to the future generation.

[82] Michael J. Balick, *supra* note 28, at 284
[83] WIPO FFM Report, *supra* note 16, at 214

III. Conservation

Preservation of TK may in turn connected to the conservation of biological diversity and the environment since the destruction of the communities living environment highly contributes for loss of TK.[84] Thus, preventing the unsustainable use or erosion of biodiversity resources on which the lively hood of TK holders depend is two edge sword that can prevent the overexploitation of for instance medicinal plants thereby supporting the continued practice of TM and associated knowledge.

IV. Prevent Unauthorized Use and Misappropriation

Another set of policy objective of protection of TK, aims at preventing the unauthorized and misappropriate use of it by third parties. The unauthorized and misappropriate use has got economic and cultural aspects. The economic aspect is the unauthorized commercial exploitation of TK without any or little benefits and compensation goes to its originators or holders. A number of patents that has been granted on genetic resources and TK obtained from developing countries including Ethiopia without the consent of the processors of the resources and its associated knowledge, are the best examples of economic exploitation of TK. In this case, protection of TK aims at avoiding '*biopiracy*'[85] and to ensure that benefits or compensation is given to its holders. Economic exploitation of TK is one piece of the puzzle. That is, the cultural aspect of appropriation is also with high priority. As briefly mentioned in the previous chapter, besides TK's economic value, it has got both sacred and cultural value. Using TK beyond or contrary to its traditional context is what we call it misappropriate usage of TK. In this regard, the purpose of protecting TK is to ensure that it is used with in its traditional context. There are several cases that illustrate misappropriation, a few of which have been discussed here.

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[84] Carlos M. Correa, *Protection and Promotion of Traditional Medicine: Implications for Public Health in Developing Countries* 30 (2002) available at http://www.southcentre.org/publications/traditionalmedicine/traditionalmedicine.pdf [accessed on June 10, 2010]

[85] '*Bio-piracy*' has been defined as '*the process through which the rights of indigenous cultures to genetic resources and knowledge are erased and replaced for those who have exploited indigenous knowledge and biodiversity*' VANDANA SHIVA ET AL., THE ENCLOSURE AND RECOVERY OF THE COMMONS 31 (1997)

A. The Neem Tree (Azadirachta Indica) of India

The Neem tree grows in India, where villagers are very familiar with its medicinal properties and call it the '*curer of all ailments'*.[86] From 1992-1995 W.R. Grace & Co., a multinational chemical corporation, received several US and European patents for applications related to the Neem tree. [87] The Indian government took legal action and the European patents were effectively overturned[88] while patents granted in US remain valid due to failure to provide written evidence that constitutes prior art.[89] This case shows the fact that despite the existence of international rules on IP matter the varying national patent standards leads to different outcomes when patents based on TK is challenged. [*See*: Section 3.2.2.1]

B. Hoodia of the San People

Hoodia cactus is an appetite-suppressant used by the san people reside in four countries in the southern part of Africa- South Africa, Angola, Namibia and Botswana. A patent for P57- the active ingredient in Hoodia- was granted to the South African council for scientific and industrial research (CSIR) based on the san local knowledge about Hoodia, later on licensed to the Pfizer- the British pharmaceutical company.[90] After the San people in South Africa threatened to sue under the CBD, the CSIR entered in to the benefit sharing arrangement with the san people.[91] This case shows an instance where TK is misappropriated by research institutions or companies of developing countries from people in their home country.

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[86] *See generally*: Linda Bullard, *Freeing the Free Tree*, (2005) available at http://www.womenandlife.org/WLOE-en/information/globalisation/neembriefmar05.html. [accessed on June 5, 2010]

[87] *E.g.* US patent No. 5,409,708 issued on April 25, 1995 relating to novel fungicide compositions prepared from Neem seeds AND Eur. Patent No. 494067 issued on august 13, 1997 granting patent for novel pesticide preparations derived from Neem oil and Neem wax fractions. For more discussion on patents on Neem tree *See:* Olufunmilayo B. Arewa, *TRIPS and Traditional Knowledge: Local Communities, Local Knowledge, and Global Intellectual Property Frameworks,* 10 MARQ. INTEL'L. PROP. L. REV. 155, 170 (2006); *See also*: Shivani Chaudhry, The Quest for Equity and Efficiency in the Use of Plant Genetic Resources 150-151 (1999) (Unpublished MA Thesis submitted to Center for Environmental Studies at Brown University)

[88] *See generally*: Bullard, *supra* note 86

[89] Arewa, *supra* note 87, at 170

[90] MCGOWN, *supra* note 70, at 8-10

[91] *See generally*: Vermeylen, *supra* note 37

C. Pirated Ethiopian Herbal Medicines

In 2004, a researcher in Tennessee (US) has obtained a US patent[92] on four medicinal plants[93] those have been used by Ethiopians for centuries. The patent makes sweeping claims for preparations of the plant extracts and against *"breast cancer, leukemia, melanoma, and myeloma and viral infection, diabetes, Parkinson's disease, tuberculosis, or fungal infections."*[94] Despite the patent, little appears new about the medicinal uses claimed for these plants.[95] It would seem that the US Patent and Trademark Office did not make much of an effort to investigate and validate the novelty of these patented inventions. Though objection was raised the patent remains valid and commercialization continued without sharing any benefits with Ethiopians.[96]

V. Equity

The underlying concept in the protection of TK at the international level is based on equity considerations. This is especially relevant in IP fora and mainly related to misappropriation. The point here is that TK generates value and income to many companies found in the developed world, since it is the basis for many modern innovations. However, due to the system of appropriation and reward currently in place, its holders do not adequately recognized and compensated. That is why the question of equity lay on the ground i.e. is it fair to ignore those who originate and maintain this knowledge and leave the benefit to big industries? Besides, the global economic imbalance backed by protection of knowledge from the developed world is at the heart of this concept. The protection of intellectual asset of developing countries- TK- therefore, is necessary to bring equity to essentially unjust and unequal relations.[97]

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[92] US patent 6,811.795 issued on 2 Nov 2004 *See*: MCGOWN, *supra* note 70, at 7

[93] *Id.* (*Glinus lotoides, Ruta chalepensis, Hagenia abyssinica* and *Millettia ferruginea* in Ethiopia locally known in Amharic *Damascisa, Tena Adam, Kosso* and *Birbira* respectively)

[94] *Id.*

[95] *Id.*

[96] Maggie Kohls, *Blackbeard or Albert Schweitzer: Reconciling Biopiracy*, 6 CHI. KENT J. INTL'L. PROP. 108, 114 (2007)

[97] Correa, *supra* note 5, at 5

VI. Promotion

The other possible policy objective of protecting TK may be the promotion of TK. The promotion of TK relates broadly to the harnessing of TK for trade and development.[98] There are several objectives which could be included under this framework. These are: promoting the use and further development of TK systems and TK based innovations; promoting appropriate and sustainable commercialization; and ensuring that a fair and equitable share of the use of TK is captured by TK-holders.[99]

3.2. Intellectual Property and TK/TMK

Intellectual Property [IP] is a generic term used to refer to a group of legal regimes, each of which, to different degrees, confers rights of ownership in a particular subject matter and devised to protect knowledge literally by granting rights to exclusion of third parties from unauthorized exploitation.[100] Copyright, patents, industrial designs, trade marks and protection against unfair competition form the traditional core of IP.

Due to multiple reasons, the twentieth century evidenced in the unprecedented international and regional agreements so as to universalize the IP system. Accordingly, there are a number of international and regional agreements designed to harmonize and sometimes to require introduction of new legal regime to protect IP. Recognizing the fact that the present globalised world is tied by the rope of information, universality of IP is not astonishing event. The Agreement on Trade Related Aspects of Intellectual Property (TRIPS)[101] represents a significant step in the globalisation of IPRs. This agreement is used as a primary reference in dealing with IPRs at the international level through out this chapter. TRIPS sets minimum standards for protection of different kinds of IPRs, which are relevant to TK/TMK i.e. patents, trade marks, geographical indications and trade secrets.

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[98] Karin Timmermans, *Intellectual Property Rights and Traditional Medicine: Policy Dilemmas at the Interface*, 57SOCIAL SCIENCE &MEDICINE 745, 749 (2003)

[99] *Id.*

[100] WIPO, WIPO INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW AND USE 3 (2nd ed., 2004) [here in after WIPO IP HANDBOOK]

[101] Agreement on Trade-related Aspects of Intellectual Property Rights, Annex 1Cof the Marrakech Agreement signed on 15 April 1994 [here in after TRIPS] TRIPS agreement is one of result of Uruguay round and part of the single undertaking agreements administered by WTO.

IPRs are seen as one possible means to protect TK including TMK both internationally and nationally. The paper will discuss the issues raised and test the feasibility of options forwarded after the next sub section. The next subsection discusses the objections raised by opponents of IP protection of TK.

3.2.1. Objections to IP Protection of TK/TMK

Some academicians and TK holders were skeptical of or were opposed to the use of the IP system to protect TK. The paper addresses these views by considering the most commonly expressed objections to the IP approach for the protection of TK and assesses their validity.

i. Tension between Policy Objective

The first objection to the appropriateness of IP to TK is the tension between the policy objectives to be secured by protection of IP and the very nature of TK. The main justification for the protection of IPRs is utilitarian or incentive theory- the goal of promoting economic efficiency, or providing incentives for innovation thereby stimulate dissemination of knowledge to the public that can be used for further innovation.[102] Alleging that innovation of TK has already occurred, it has been argued that traditional peoples did not need incentives in the form of modern IPRs to develop TK.[103] The fact as mentioned everywhere in this paper, however, is that TK is not ancient but dynamic that has had a recent burst of innovation. As OseiTutu rightly noted, the innovation IP seeks to promote and the innovative aspects of TK differ.[104] To be precise TK, is said to be innovative insofar as it is constantly evolving in response to a changing environment, to borrow his words it can be better described as '*adaptive rather than truly innovative'*.[105] Though the goal of the incentive may differ, one could list the objective to give incentive as shared policy objective of IP and TK protection.

The concept of incentive to inventions in the area of pharmaceutical products is a thorny issue to developing countries, which needs serious consideration. There are diseases which are

[102] J. Janewa OseiTutu, *A Sui Generis Regime for Traditional Knowledge*, University of Pittsburgh Legal Studies Research Paper Series Working Paper No. 2010-12, 13 (2010) (Noting that the modern discourse on IP often focuses on innovation and creativity as the utilitarian goals of intellectual property policy.)
[103] Stephen R. Munzer & Kal Raustiala, *The Uneasy Case For Intellectual Property Rights In Traditional Knowledge*, 27 CARD. ARTS & ENT. L. J.37, 73 (2009)
[104] OseiTutu, *supra* note 102, at 23
[105] *Id.*

more common to poor peoples and the tropical area. Researches revealed that the patent system is not incentivizing development of new drugs for the developing world- i.e. very little researches are directed to the disease burden of the developing world, and yet insignificant numbers of new drugs are invented that responds to the health needs of peoples in these countries.[106] This is due to the fact that Patents are tools for generating inventions assumed to be exploited in markets. [107] There is, hence, a need to shift to give incentive to grass root innovations based on TMK- the knowledge system which is familiar to the problems of the area, if the health needs of the poor people needs to be satisfied.

ii. Collective TK and Individual IP

It is argued that since TK is trans-generational and collectively held while IP require that an individual author be identified, the IP system a priori excludes TK.[108] But this is a simple generalization. First, not all TK is collective. Any assumption that there is a generic form of collective/community TK ignores the intricacies and sheer diversity of TK systems.[109] Similarly, not all IPRs are individualistic. Increasingly, invention and creation take place in firms where groups of persons may be cited as co-inventors or co-authors, concepts recognized by the IP system. Trademark law recognizes "collective marks" and geographical indications also protect the interests of a collective. This suggests that this argument which

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[106] Patrice Trouillier, et al., *Neglected Diseases and Pharmaceuticals Between Deficient Market and Public Health Failure*, 2 (2001) *cited in* Bruce Lehman, *Patents and Health*, Discussion Paper presented to the Policy Advisory Commission of the World Intellectual Property Organization, International Intellectual Property Institute, Beijing, China, 21 (2002) available at http://www.wtplaw.com/public_document.cfm?id=238 [accessed on September 8, 2010][noting that 1 *percent* of 1,191 new drugs approved for marketing between 1975 and 1999 were specifically indicated for a tropical disease.] For contrary statistics and argument *See:* Felix Rozanski, *Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Reality*, The Stockholm Network Experts' Series on Pharmaceutical Intellectual Property Rights, Stockholm Network (2007) [relating the improvements in the human development index (HDI) of developing countries to the protection of IP]

[107] IMS Health, *Market Report* (2001) available at http://www.ims-global.com/insight/report/global/report.htm. [accessed on September 8, 2010] It is estimated that the US, EU and Japan account for 80 *percent* of global market for pharmaceutical products, while the rest of the world combined represent only 20 *percent* of the market. If there are no markets for an invention, it is unlikely that the requisite investment leading to the commercial exploitation of a patent will be made. Hence, commercial pharmaceutical research and development is being overwhelmingly directed to produce patented drugs which will meet patient needs in a handful of countries in the developed world. Clearly, the problem faced by poor countries is that they do not constitute a market capable of inducing big pharmaceutical industries for patent-driven solutions to their health problems.

[108] Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVT'L. L. & POL'Y 219, 232 (2008)

[109] *Id.*

considers TK and IP inherently incompatible is not a valid assertion to *a priori* exclude TK in general from the discussion of IPRs.

iii. Prohibitive Costs

One of the criticisms forwarded against the IP system is the cost of acquisition, maintenance and enforcement of IPRs. The lack of economic self sufficiency of many traditional communities, the unequal power relation between them and the corporate world and the high cost of acquisition, maintenance, enforcement and litigation of IPR would make it very difficult and even prohibitive for them to acquire and protect their IPRs.[110] As WIPO rightly asserted, costs associated with use of the IP system do not make the system inherently unjust, particularly if ways can be found to lower costs or to assist indigent persons and communities to use the system if they wish.[111]

3.2.2. Towards Positive IP Protection of TMK

Different types of IPR models are claimed to be appropriate for the protection of TK by giving exclusive rights to the holders thereof- positive (offensive) protection. Patents, trade secrets, trade marks and geographical indications are specifically relevant to TMK. Following will be analysis of the interface between TMK and each forms of IP.

3.2.2.1. Patents

Patents are designed to stimulate innovation by granting exclusive property rights to the inventor of a novel product. [112] In essence, patents create monopolies. Under the TRIPS agreement, countries are broadly obliged to provide patent protection "*for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."*[113] The substantive requirements for patent protection, according to this agreement, are that an invention be new; involve an inventive step and capable of industrially applied.[114] Though there are important differences among national laws on the subject matter of patent protection, at least in principle, patents

[110] Wilder, *supra* note 60, 21
[111] WIPO FFM Report, *supra* note 16, at 222
[112] Dwyer, *supra* note 108, at 231
[113] TRIPS Agreement, Article 27.1
[114] *Id.*

may be applied to different components of TM, provided that the above mentioned patentability requirements are met.

I. Novelty

Novelty is the prerequisite to enable the protection of TMK under the patent law. Novelty is assessed with reference to prior art or state of the art.[115] Prior art refers to the complete body of knowledge which is available to the public before a patent application.[116] The existence of prior art destroys the novelty of an invention. It is a disputed question whether TMK constitutes prior art or not. There is no definite answer given the diversified characteristics of TMK and national patent regimes. There are two major modes regarding the determination of prior art- the universal/absolute and relative novelty requirement.

In countries where a relative novelty standard is applied, disclosure in a non-written form other than the country where the patent is claimed may not be an obstacle to obtain patents on TM.[117] This means, TMK that has been published in a written form any where in the world is not patentable. If such knowledge was publicly used but not documented in a foreign country, novelty is not lost and patenting remains possible. Therefore, there is a possibility for acquiring a patent for those TMKs that have been transmitted orally if other criteria are met. At the same time it also has a danger of creating a room for biopiracy. As mentioned in the previous section, this is a case in U.S., where several patents relating to TMK acquired in developing countries, have been granted to researchers or firms by the US Patent and Trademark Office.

The universal novelty requirement, as applied in most countries including Ethiopia, prevents the patenting of information that has been published in a written form or has otherwise been made available to the public either through oral disclosure or disclosure by use, *in any*

[115] WIPO IP HANDBOOK, *supra* note 100, at 19
[116] *Id.*
[117] In the United States, for instance, according to article 102 of the Patent Law (35 United States Code),
'A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States...'

country.[118] A significant part of TMK has been disclosed as a result of codification, wide use, or through collection and publication by anthropologists, historians, botanists or other researchers and observers. Hence, a large portion of TMK held by local/indigenous communities, and codified TMK, is likely to be deemed not to be novel and therefore not patentable.

Nonetheless, in order to destroy novelty, Correa noted that the prior use must generally be such that access to the information would have allowed a third party to execute the invention, without significant further research.[119] Thus there may be situations in which novelty may not be lost, despite the relevant TMK having been previously used, even for long periods.[120] Xuan shares this view by giving an illustration of TMK known and used by the minority ethnicities in China in which the knowledge has not diffused and inaccessible beyond the community members.[121] Cases where traditional healers have kept confidential, certain aspects of their treatment and associated medicines may be another example. Generally, meeting the requirement of novelty remains a challenge for most TMK to get IP protection. However, it would be incorrect to assume that all TMK, because it may be old and previously used, has necessarily lost its novelty for the purposes of patent law.

II. Inventive Step (Non Obviousness)

When certain TMK has remained undisclosed or in any case the novelty of the information is preserved- an additional standard of patentability must be met in order to acquire patent rights: 'inventive-step' or 'non-obviousness'.[122] This standard requires that the claimed invention be non-obvious for a person with ordinary skills in a given technical field.[123] With regard to the conditions to be considered in assessing non obviousness, different parameters are employed in different countries depending on the national law under which a patent is claimed. In any case a comparison has to be made between the claimed invention and the

[118] *See e.g.,* Art. 3(2) of Ethiopian Inventions, Minor Inventions and Industrial Designs Proclamation, Proclamation No. 123/1995
[119] Correa, *supra* note 84, at 55
[120] *Id.*
[121] Xuan Li, *Novelty and Inventive Step: Obstacles to Traditional Knowledge Protection under Patent Regimes: A Case Study In China*, 29(4) EUROP. INTEL'L PROP. REV. 134, 135(2007)
[122] TRIPS Agreement, Article 27.1
[123] WIPO IP HANDBOOK, *supra* note 100, at 20

prior art, if any.[124] In doing so, the problem to be solved, the solution to the problem and the advantageous effect, if any, of the invention with reference to the prior art is considered.[125]

Since, TMs are usually crude materials that are processed simply and do not involve sophisticated know-how, it is widely recognized that the difference between the prior art and the claims at issue is difficult- both technically and practically- to determining based on the problem, solution and effect test.[126] To relieve this problem, different loose standards to TM other than the one already put in place for modern pharmaceutical products are proposed and even adopted in some countries. For instance, the *product by process* model is adopted by Chinese patent law in the context of TMK, as it can be better described by the process by which it is obtained and not by its elements and structure.[127] According to this model, protection is only extended to a product obtained with the claimed process; the same product if obtained by another process would not infringe an existing claim, which makes the patent significantly weaker than patent on other modern pharmaceutical products.[128]

Whether states will follow similar way of smoothing the inventiveness standard so that they will grant patents for allegedly minor or trivial developments, depends on the philosophy underpinning the patent system in each country, and on the objectives pursued. Nonetheless, some authors object the idea alleging that little portion of the society may reap all the benefit by extending legal monopolies to holders of TMK, or to those that obtained knowledge from them, where no genuine invention can be claimed.[129] Given the market disruption effect and high costs that patents granted on low or non-inventive developments, developing countries

[124] WIPO IP HANDBOOK, *supra* note 100, at 20
[125] *Id.*, at 21
[126] Xuan, *supra* note 121, at 138 Technically speaking, the simplicity of the claimed invention coupled with the failure to describe the invention in structural terms by specifying their chemical composition- unlike chemical pharmaceutical products- may potentially destroy the non obviousness requirement. Similarly, if inventiveness is said to be examined based on the processes used in TM i.e. addition (deduction), substitution, combination or modification in quantitative proportion of the substances used, it will pose practical problem of contentious infringement claims as evidenced in china.
[127] *Id.*
[128] *Id.*
[129] Correa, *supra* note 84, at 58

are suggested to set high standards for inventive step.[130] If this is the case, it becomes difficult to TMKs to gain protection by IP.

III. Procedural Requirement (Disclosure of the Invention)

In addition to the three substantive requirements a patent claim needs to meet, there is also one procedural requirement a patent application required to satisfy. Article 29(1) of the TRIPS agreement obliges patent applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. That is, the patent specification must be written in a technical way that patent examiners can understand.

This is a situation that gives companies an advantage since it would be extremely difficult for TMK holders to translate their knowledge in to technical language so as to complete the patent specifications though useful characteristics of a plant or animal may be well known though.[131] Here there is a role for qualified attorneys and experts to assist in translating the knowledge in a patent application. But it may increase the cost of application that would aggravate the situation of allegedly unaffordable cost of filing, which is unlikely. There shall be considerable assistance from the respective government or other international mechanism so that TMK holders could be able to use the system.

Generally, the aforementioned discussion shows that using the existing patent system for the protection of TMK is tremendously difficult. But this does not mean that the door is completely closed. Still there is a space no matter how the gap widens and shrinks in different countries. Therefore, it is up to the states to stretch the space. However, this is not supposed to mean that action at the international level is irrelevant, rather it is fundamentally crucial. One thing that needs consideration here is that the door for further misappropriation may be considerably opened in the effort to incorporate TMK within the patent matrix that should be seen cautiously.

3.2.2.2. Trade Secrets

Trade secret protection is potentially another mechanism for the protection of TMK through IPR. Broadly speaking, trade secrets are any business information that is kept confidential to

[130] *Id*.
[131] Dutfield, *supra* note 34, at 255

maintain an advantage over competitors and its disclosure would harm the interest of the business.[132] This valuable information is protected through the laws of trade secret or undisclosed information, if it complied with the conditions required by law. Though, the conditions may vary from country to country, some general standard requirements exist at the international level which are referred in to Article 39(2) of the TRIPS Agreement. These are: 1) The information must be secret (i.e. it is only known among, or readily accessible to, circles that normally deal with the kind of information in question); 2) It must have commercial value because it is a secret; and 3) It must have been subject to reasonable steps by the rightful holder of the information to keep it secret. With regard to the type of protection, trade secret laws prevent unauthorized disclosure and use of the trade secret by persons other than the right holder.

How trade secret laws can protect TMK? As said else where, much of TMK is disclosed to the public either through publications or use. There is, however, cases where traditional healers deliberately kept their knowledge secret and known among only a small, closed circle of traditional healers or is passed down generation-to-generation within a family.[133] The knowledge may not be generally known and may, therefore, be protectable as a trade secret so that they can take legal action on those who misappropriate it.

Trade secret protection has many advantages to the right holders, especially for TMK, if possible. First, *registration* is not needed in order to acquire the rights conferred under trade secrets law,[134] only a reasonable effort to keep the secret and/or declaring that the details are secret is enough.[135] Second, a trade secret need not meet the more formal, rigorous standards for patent protection of 'novelty' and 'inventive step'; that would exclude it from patentability. Fourth, unlike other forms of IPRs in which protection is limited by time, a trade secret can, if kept secret, its protection last in perpetuity.[136] This feature is especially

[132] BRYAN A. GARNER (ED.), BLACKS LAW DICTIONARY, 1501 (7th ed. 1999)
[133] Correa, *supra* note 84, at 71
[134] WIPO, *Trade Secrets: Policy Framework And Best Practices*, WIPO MAGAZINE, May 2002, at 17 (There is no government registration process in any country of the world that forces enterprises to reveal their confidential business in formation to the authorities in order to obtain trade secret rights.)
[135] N. Stephan Kinsella, *Against Intellectual Property,* 15(2) J. LIBERTARIAN STUDIES 1, 6 (2001)
[136] For instance patent protection is granted for only 20 years after the filing date of the patent application.

appropriate to TMK that has remained secret and must remain so due to cultural or religious factors.

There are, however, some concrete disadvantages of protecting secret TMK as a trade secret. In trade secret law, protection is available only against a wrongful acquisition, use, or disclosure of the trade secret. It does not provide the exclusive right to possession or use and exclude third parties from making commercial use of it.[137] Once the product is commercialized, anyone may have access to it and use it at will. In doing so, they may be able to inspect it, dissect it and analyze it to determine how it works or how it was made or manufactured and finally discover the secret. This is what we call reverse engineering.[138] As long as acquisition of the product is by fair and honest means, a person may legally obtain information underlying a trade secret by reverse engineering.[139] This is a precarious issue especially to TMK. TMs are mostly a simple composition of herbs or other substance that can be easily detected by modern science. Thus, they are more likely to be discovered by reverse engineering so that it can be legally produced by third parties. If that is the case, it will defeat the very essence of protection. Moreover, though acquiring the right incur no payment at all, financial and technical capacity is necessary to keep the information secret and to enforce the right.[140]

In general, it can be said that the possibility exists for trade secrecy to be deployed as a means to protect some TMK and to realize its commercial potential. Notwithstanding the theoretical suitability of trade secret law to the protection of TMK, it seems practically problematic to achieve the objective of protection.

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[137] P. Samuelson & S. Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L. J. 1575, 1583 (2002)

[138] Thomas Dougherty, *Common Defenses in Theft of Trade Secret Cases*, 57(2) US Attorneys' Bulletin 27, 31(2009)

[139] *Cf.* Samuelson & Scotchmer, *supra* note 137, at1577 (discussing that TRIPS neither requires nor sanctions a reverse engineering privilege)

[140] WIPO summarizes the cost of protecting trade secrets to include the cost of putting in place an information security and protection policy and program in the company and the cost of monitoring, surveillance, audit and legal measures in the costly and lengthy court procedures against insiders or outsiders who breach or try to breach the security system. *See*: WIPO, *Trade Secrets: Policy Framework And Best Practices*, WIPO MAGAZINE, May 2002, at 17

3.2.2.3. Trade Marks and Geographical Indications

Trademarks are words, signs, symbols or combinations thereof that identify goods as manufactured by a particular person or a company, therefore allowing consumers to distinguish between goods originating from different sources.[141] At its core, trade mark once registered gives the right to prevent others from using the same or similar marks on the same or similar products.[142] Trade marks may have some relevance to the protection of TMK. Considering the collective nature of substantial part of TMK, Correa prefer to special types of trade marks- collective marks[143] and certification marks[144]- as more suitable.[145]

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation due to their place of origin.[146] The TRIPS agreement sets the standard level of protection to geographical indications of all products in order to avoid misleading the public and to prevent unfair competition.[147] Geographical indications may be useful to enhance the commercial value of TMs, whenever the consumer can establishes an association between the geographical origin and the characteristics or quality thereof, and hence prevent parties and products not originated from that geographical area from using such indications to the extent that prohibits public misleading. For geographical indications of wines and spirits TRIPS provides for a higher or enhanced level of protection (subject to some exceptions, they have to be protected even if misuse would not cause the public to be misled).[148] Issues are being debated in the TRIPS Council under the Doha mandate to extend the higher level of protection to other products.[149]

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[141] *See:* Art. 15 (1) of the TRIPS Agreement
[142] Art. 16 of the TRIPS Agreement
[143] '*Collective marks are trademarks which serve to distinguish the geographical origin or other common characteristics of goods or services of different enterprises which use the collective mark under the control of the owner.' See* Wilder, *supra* note 60, at 17
[144] '*Certification marks are trademarks used to identify a product which meets certain standards established, managed and enforced by an organization "competent to certify" the products concerned.' See Id.*
[145] Correa, *supra* note 84, at 74 (noting that the use of collective marks or certification may have the benefit of providing a specific badge of approval of a local or indigenous community, in addition to give an indication of geographically dependent qualities of products.)
[146] Art. 22(1) of the TRIPS Agreement
[147] Art. 22(2) of the TRIPS Agreement
[148] Art. 23 of the TRIPS Agreement
[149] *See*: WTO, Doha Ministerial Declaration of 14 November 2001, at Para. 18, WT/MIN(01)/DEC/1[here in after Doha Declaration]

There is no subject matter incompatibility between TK and trade mark and geographical indications. However, in a strict sense, any of these IPRs do not protect the knowledge incorporated in the products, i.e. they do not impede the commercialization of imitative product under a different trademark or geographical indication, or without having thereof, by third parties. As long as there are potentially competitive similar products, protection by such signs do not automatically guarantee that they would generate added value for the right holders, rather it is instrumental. In other words, the effectiveness of these modalities of protection as a means of promoting the commercialization of TM will depend on the title holders' capacity to establish and preserve product homogeneity and quality standards, and on investments in promotion and marketing so as to assume good reputation.[150] Especially, usage of signs collective in nature needs adequate standards to be applied and monitoring mechanisms to ensure that the characteristics and quality of products conform to such standards.[151] They must also exercise their rights both domestically and internationally, so as to deter the commercialization of infringing products. It would be vain to say that all this are possible to most TMK holders, without significant state support or other mechanisms.

3.2.3. Defensive Protection/Misappropriation Regime

One possible approach to protection of TK is to take measures that make impossible (or more difficult) for third parties to claim and acquire formal property rights over TK, especially the grant of bad patents. This is what is meant by defensive protection, some time referred as the misappropriation regime. Though defensive protection can be used to deter misappropriation or unauthorized use of TK by different IP modalities, it is mainly associated with patents, especially in the case of TMK. The principal types of defensive protection are making TK-related information that may constitute prior art available to patent examiners and/or increasing the burden of disclosure in patent applications.

3.2.3.1. Making Information Available to Patent Examiners (Documentation)

To be patentable an invention has to be novel that is considered to be destroyed by the existence of prior art. There are a number of cases where pharmaceutical companies acquire

[150] Correa, *supra* note 84, at 75
[151] *Id.*

patents for application of TMK which constitute prior art. Different reasons can be attributed to this problem. First, much of TK is found in unwritten form, while in some countries with relative novelty requirement, patenting by unauthorized third parties (biosquaters) remains possible. Documentation of TK is important in order to defeat this kind of problem. Once documented it is possible to challenge patents, if granted. Second, though written documents are available, they may not be organized in a way that patent examiners can easily access them.[152] Thus, documentation in organized manner will facilitate access to patent examiners so that *a priori* prevent the grant of bad patents, thus, relieve TK holder from challenging the patent in substantially costly and lengthy court procedures.

For that matter, some countries have begun to create traditional knowledge databases (TKDs). In this regard, India's TK Digital Library (TKDL)[153] and Traditional Chinese Medicine Patents Database (TCMPD)[154] are the two remarkable examples. At the international level, the World Bank has started to collect African and other regional indigenous knowledge in a database with the objective of hosting an international storehouse of global prior art.[155] This increases the likelihood that patent examiners locate already published TK that is relevant to claimed inventions in patent application.[156] Documentation is also an important tool to the preservation of TK that are on the verge of extinction.

The problem with such documentation for defensive protection purpose, however, is that it will imply public disclosure in turn raises IP related questions. Public disclosure, under patent and trade secret laws generally bars any possibility of acquiring formal protection, therefore denies TK holders the possibility to procure IP protection.[157] In addition, this disclosure will facilitate biosquaters to easily access the knowledge, therefore legally commercialize with out

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[152] Carvalho, *supra* note 22, at 248

[153] TKDL is easily navigable computerized database of documented TK relating to the use of medicinal and others plants and practices. Available at http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng [accessed on May 20, 2010] [*See*: section 3.4.1/I]

[154] TCMPD is online database system which records traditional Chinese acupuncture, herbal medicines, animal-derived drugs and mineral drugs in a format searchable by patent examiners. Traditional Chinese Medical Databases Online System, http://wall.cintcm.ac.cn/webdkrhl/e_index.htm [accessed on May 20, 2010]

[155] *See generally:* Vermeylen, *supra* note 37, at 145

[156] *Id.*

[157] Carvalho, *supra* note 22, at 248

claiming IP protection.[158] Nothing will also prohibit biosquaters from patenting their invention based on freely accessed TK so long as they made a significant change that constitutes novel and inventive step.[159] As Chander and Sunder rightly points, it would be a '*nice bow tied gift'* for western companies.[160] Therefore, holders of TMK- especially with secret knowledge- may refuse to release information in their control. While squatting of TK in other countries will not prevent holders of TMK from continuing to use in their daily life, documentation for the sole reason of opposing patents without any return will be economically a waste of resources due to the costs entail in the creation and management of the documents.[161]

Therefore, there is a need to manage the downside risks of disclosure and ensure that TK holders benefit from such disclosure. One way to do so is to limit the accessibility of the documents only to patent examiners in their search of prior art. For those who need to access the documents, benefit sharing arrangements from the commercialization of the knowledge accessed shall be employed. This is an approach taken by India that has decided to make TKDL available only to patent examiners under a non disclosure agreement.[162]

3.2.3.2. Increase the Burden of Disclosure in Patent Application (Disclosure Requirement)

This is an idea setting its foundation in the provisions of the CBD related with access and benefit sharing (ABS). [ABS regime will be further discussed in the next section.] For the time being it is enough only to have a birds-eye view of the core concept enshrined with in it. Fair and equitable sharing of benefits arising out of the utilization of genetic resources is one of the three pillar objectives of the CBD.[163] One way of securing this is through ABS agreement. According to article 15 of the convention access to genetic resources should be based on the prior informed consent of (PIC) of the owners, on mutually agreed terms and

[158] WIPO Publication No. 920(E), *supra* note 30, at 26
[159] *Cf*. Munzer & Raustiala, *supra* note 103, at 82 (notes documented TMK is still prior art only with respect to some actual or possible inventions, but not that anticipates the new drug based on that knowledge)
[160] Chandert & Sunder, *supra* note 8, at 1362
[161] Carvalho, *supra* note 95, at 248
[162] WIPO, Report of the Fourth Session of the IGC, at Para. 140, WIPO Doc. No. WIPO/GRTKF/IC/4/25 (Dec. 17, 2002)
[163] The other two are the conservation of biological diversity and sustainable use of its components. Art. 1 of the CBD

benefit sharing arrangement. This mechanism is also extended to access TK that is recognized by the convention and member states are obliged to grant protection.[164]

The disclosure requirement discussed underneath is principally aimed at supporting the full implementation of the ABS agreement so that it ensures that access to TK is carried out in conformity with the three conditions of access - PIC, mutually agreed terms and benefit sharing. But, it can also prevent the granting of bad patents that are based on TK. For that matter, proposals have begun to emerge to change the procedures of patent application, if an invention is based on TK. More certainly, patent applicants must indicate in their patent application: i) the source and country of origin of TK used in the invention; ii) evidence of PIC from the authorities under the relevant national regime; and iii) evidence of fair and equitable benefit sharing under the relevant national regime.[165]

There are ardent proponents and opponents to this disclosure requirement. Those who oppose, raise both practical and theoretical problems to apply the requirement. The first objection is the assertion that the measure is incompatible with the TRIPS agreement, which provides procedures and formalities required as a condition for acquisition of IPRs to be reasonable and consistent with the provision of the agreement.[166] Though what is reasonable procedure is not clear from the text of the provision, citing the panel decision Carvalho concluded that '*it is self evident'*.[167] He argued that since article 27 admits no exception, the need to implement the CBD does not make the requirement reasonable.[168] Besides, he adds, while WTO includes members that are not contracting parties to the CBD it would not be reasonable to impose on those members an obligation they are not bound to implement and do not wish to do so.[169] Therefore, member states can not impose disclosure as a legal prerequisite for granting patents.[170] Counter arguments rely on a more interlinked and reasonable interpretation of

[164] CBD, Art. 8(j)
[165] WTO TRIPS Council, *the Relationship between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made*, at 28, WTO Doc. IP/C/W/368/Rev.1 (2006)
[166] Article 62 (2) of the TRIPS agreement
[167] Carvalho, *supra* note 22, at 252
[168] *Id.*
[169] *Id.*
[170] *Id.*, at 253

Articles 1,[171] 8.1,[172] 27 and 62 of the TRIPS which would result in the acceptance of this type of measure.[173]

In addition to problems related to compatibility with international IP laws, practical problems are also raised. For instance, Hanns reflects US's fear that the disclosure requirement would introduce many negative consequences including the addition of new uncertainties into the patent system, imposing significant administrative burdens on states and undermining the role of the patent system in promoting innovation.[174] In the other side of the spectrum, those states advocating for the disclosure requirement hold the view that it would rather make the patent system more transparent.[175]

There are different ongoing initiatives in different international fora so as to establish international legal machinery to the disclosure requirement. The discussion in each forum is characterized by polarized views. [See: Section 3.4.2.] The effectiveness of disclosure requirement in preventing acquisition of bad patents depends on the success of international negotiations. Other wise, unilateral incorporation of disclosure requirement in national patent laws will not be efficient in deterring biosquaters from acquiring patents based on TK in those countries who do not incorporate disclosure requirement in their patent law.

3.3. Benefit Sharing

The CBD at its preamble recognizes *'the close and traditional dependence of indigenous and local communities embodying traditional life styles on biological resources and the need for fair and equitable sharing of benefits arising from the use of traditional biodiversity related knowledge.'*[176] In the substantive provisions, it also goes to impose an obligation on the contracting parties to:

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[171] Art. 1 allows members to apply the provisions of the TRIPS agreement according to their own legal practice and as such would allow the inclusion of the disclosure.

[172] Art. 8.1 allows the flexible interpretation of the agreement in order to provoke measures that serve the public interest.

[173] Vermeylen, *supra* note 37, at 143

[174] Hanns Ullrich, *Traditional Knowledge, Biodiversity, Benefit Sharing and Patent System: Romantics V. Economics?* EUI Working Paper Law No. 2005/07, 25-29 (2005)

[175] Krishna Ravi Srinivas, *Traditional Knowledge and Intellectual Property Rights: A Note on Issues, Some Solutions and Some Suggestions*, 3 ASIAN J. WTO & INT'L HEALTH L. POL'Y 81, 92 (2008)

[176] CBD, Preamble Parag. 13

> *[…] [R]espect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional life styles relevant for the conservation and sustainable use of biological diversity and to promote their wider application with the involvement of the holders of such knowledge, innovations and practices […]*[177]

Given the fact that fair and equitable benefit sharing is one of the pillar objectives of the convention, the same provision obliges members to '*encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.* '[178]

As the CBD is a frame work convention, which only provides the bare bone principles to be applied, details are laid down in further protocols; thus, details about how TK should be protected and equitable benefit sharing is achieved is not incorporated under the convention.[179] In order to address the implementation of these issues, the conference of the parties (COP)[180] establish two ad hoc open ended inter-session working groups, in which the working group on Access and Benefit Sharing(ABS-WG)[181] is directly concerned with the issue at hand. Based on the recommendation of the ABS-WG, in 2002 COP-6 adopted Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn guidelines).[182] According to the Bonn guideline, access to genetic resources and associated TK shall be made based on prior informed consent, mutually agreed terms and benefit sharing agreement.[183] However, the guidelines are not mandatory. Rather they are only guidelines to be used as an input in drafting national laws

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[177] CBD, Art. 8(j)
[178] *Id*.
[179] Azmi Sharom, *A Critical Study of the Laws Relating to the Indigenous Peoples of Malaysia in the Context of Article 8(j) of the Biodiversity Convention*, 13 INT'L J. ON MINORITY & GROUP RTS. 53, 56 (2006)
[180] The COP is the governing body of the CBD and takes decisions on the implementation of the different provisions of the Convention.
[181] The ad hoc working group on Access and Benefit Sharing was established by the COP-5, in May 2000, in Nairobi, Kenya. *See*: Decision V/26 of the Fifth Meeting of the Conference of the Parties to the CBD, UNEP, Annex III 66, at 196-204, UN Doc. UNEP/CBD/COP/5/23 (2000)
[182] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Conference of Parties to the Biodiversity Convention, Decision VIII/4, April 2002. The full text of the guidelines is available at http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24 [accessed on February 23, 2010]
[183] *Id.*, Part IV

relating to ABS.[184] Many countries including Ethiopia already have developed national ABS laws.

Now the ABS-WG has finalized its task of developing international ABS regime and presents the draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to COP 10 recently held in Nagoya, Japan 18-29 October 2010.[185] After several years of hard-scrabble negotiation and two weeks of strenuous meetings at Nagoya, in the early hours of 29 October 2010, the first international ABS regime was adopted which is entitled as '*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'*[186] [Nagoya Protocol]. It will be open for signature from February 2, 2011, to February 1, 2012,[187] and is to take effect 90 days after the 50th party has ratified it.[188]

Adoption of the Nagoya Protocol is perfectly a remarkable progress as it addresses issues that have pitted countries of the North and South against one other for decades. It calls for the fair and equitable sharing of benefits arising from the utilization of genetic resources and associated TK.[189] The Nagoya protocol reiterated the terms of the Bonn guideline that requires states to:

> '*take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.'*[190]

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[184] *Id.*, Part I/A
[185] Information on the tenth conference of parties to the CBD is available online at http://www.cbd.int/cop10/ [accessed on November 2, 2010]
[186] *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, decision X/III of COP- 10,(UN Doc.* UNEP/CBD/COP/10/L.43/Rev.1 Annex I [here in after Nagoya Protocol] the full text of the protocol is available at http://www.ip-watch.org/weblog/wp-content/uploads/2010/10/cop-10-05-en-Plenary-doc-25-10.doc [accessed on November 2, 2010]
[187] *Id.*, Art. 26
[188] *Id.*, Art. 27
[189] *Id.*, Art. 4(4)
[190] *Id.*, Art. 5 bis

Generally speaking, the ABS regime under the Nagoya protocol or anywhere else tries to structure the former free access to fair access. Three basic concepts are enshrined under this fair access regime- prior informed consent (PIC), mutually agreed terms and fair and equitable benefit sharing. PIC is a principle that require a third party who wants access TK to previously request authorization- depending on the law of the country- either from its holders or the competent national authority, by giving enough information about the purposes, risks and implications of the activity that is to be carried out.[191] Subsequently, authorization acquires its full life through the conclusion of agreement on mutually agreed terms that provides for fair and equitable sharing of the results and the benefits of commercialization and utilization.[192] The benefit may be monetary and/or nonmonetary that depends on the case and the agreement.[193]

The over all structure of the Nagoya Protocol gives due emphasis to the communal nature of TK. However, it doesn't generally disregard the diversity of circumstances in which TK is held or owned in different indigenous and local communities.[194] In this regard, member states are required to take in to consideration indigenous and local communities' customary laws, community protocols and procedures with respect to TK, in implementing their obligation under the protocol.[195]

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[191] Laurel A. Firestone, *You Say Yes I Say No; Defining Community Prior Informed Consent under the Convention on Biological Diversity*, 16 GEO. INT'L ENVTL. L. REV. 171,185 (2003); *see also:* Gerard Bodeker, *Traditional Medical Knowledge Intellectual Property Rights and Benefit Sharing*, 11 CARDOZO J. INT'L & COMP. L. 785, 806 (2003)

[192] WIPO Publication No. 920(E), *supra* note 30, at 23

[193] Bonn Guidelines, Appendix II and Nagoya Protocol, Annex I
Monetary benefits may include, but not be limited to: Access fees; Up-front payments; milestone payments; Payment of royalties; License fees in case of commercialization; Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; Salaries and preferential terms where mutually agreed; Research funding; Joint ventures; Joint ownership of relevant IPRs.
Non-monetary benefits may include, but not be limited to: Sharing of research and development results; Collaboration, cooperation and contribution in scientific research and development programmes, where possible in the provider country; Participation in product development; Collaboration, cooperation and contribution in education and training; Transfer of technology under fair and most favorable terms; Institutional, material and human resources capacity-building; Access to scientific information; Contributions to the local economy; Research directed towards priority needs, such as health and food security; Institutional and professional relationships and subsequent collaborative activities; Food and livelihood security benefits; Social recognition; Joint ownership of relevant IPRs.

[194] *Id.*, Preamble parag. 21

[195] *Id.*, Art. 9(1)

What is interesting in the Nagoya protocol is its observance of the situations where specific TK can be shared by more than one community in different countries. For that matter, it calls members to endeavor to cooperate with participation of the concerned local communities.[196] Furthermore, global multilateral benefit sharing mechanism is proposed for consideration to address the fair and equitable sharing of benefits derived from the utilization of TK that occur in transboundary context or where it is not possible to grant or obtain PIC.[197] The need for and the modalities of a global multilateral benefit-sharing mechanism is entrusted to be considered by the newly established Intergovernmental Committee for the Nagoya Protocol.[198]

In order to effectively implement the provision of the protocol, it obliges states to take the necessary measures to provide that TK utilized with in their jurisdiction has been accessed in compliance with access regulations of the country of origin.[199] In order to address non compliance, putting the same measures is also required and, in cases of alleged violation of domestic access legislations and regulatory regimes states are obliged to cooperate for implementation thereof. [200] The major draw backs of the Protocol is its use of vague modification terms that requires states to act in accordance with their national law and as far as appropriate which leaves much detail to the individual judgment of state parties.

WIPO is also working to develop international ABS regime. The document prepared by WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore[201] [WIPO-IGC] for discussion and negotiation aimed at, among other things, ensuring PIC and exchange of TK based on mutually agreed terms and promoting equitable benefit sharing.[202] The document further requires the principle of PIC to

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[196] *Id.*, Art, 8(2)
[197] *Id.*, Art, 7 bis
[198] COP- 10 also decides to establish an Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. *Decision X/III of COP- 10, at 3, UN Doc.* UNEP/CBD/COP/10/L.43/Rev.1 [Annex II of this decision provides the work plan of the committee]
[199] Nagoya protocol, Art. 12 bis (1)
[200] *Id.*, Art. 12 bis (2) & (3)
[201] WIPO-IGC is an ad hoc open ended intergovernmental committee established in 2000 to serve as a forum for WIPO member states for discussions relating to IP and TK. *See*: Section 3.4.2 dealing with WIPO's initiative
[202] WIPO, *The Protection of Traditional Knowledge: Revised Objectives and Principles*, Document prepared by the Secretariat to the Sixteenth Session of the IGC, ANNEX Part I, WIPO Doc. WIPO/GRTKF/IC/16/5 (March 22, 2010) [here in after WIPO-IGC Working Document]

govern any access to TK.[203] With regard to the benefits, it distinguished between usage for commercial/industrial purpose and usage for non-commercial purpose. In case of usage for non-commercial purpose, the benefits need only give rise to non-monetary benefits.[204] Like the Nagoya protocol, which requires states to pay due regard to emergency situations,[205] the document limits the application of any protection, not to adversely affect i) *the continued availability of TK for the customary practice, exchange, use and transmission of TK by TK holders; ii) the use of traditional medicine for household purposes; use in government hospitals, especially by TK holders attached to such hospitals; or use for other public health purposes*[206]. This kind of exception and limitation is essentially important for many poor people of the world to whom TM is the only affordable and available treatment.

The benefit sharing mechanism, if fully implemented is a good machinery to reap the commercial value of TK. Especially, if supplemented by the disclosure requirement discussed above, it will be more fruitful. Nonetheless, its effectiveness basically depends on the availability of effective monitoring mechanism that oversees the implementation of the ABS agreement and dispute settlement mechanisms to provide remedies in cases where, for instance, the benefits has not occurred. Unless other wise, despite its title 'Access and Benefit Sharing', as Thomas and Marion rightly observed, it will end up with opening access to TK while dropping the phrase benefit sharing.[207]

3.4. Sui Generis Regime

From the preceding discussions, one can draw the difficulties, if not impossible, of the existing IPRs to effectively protect and address many of the problems rose relating to TK. Thus, there have been suggestions and proposals to develop *sui generis* (of its own kind) system of protection- a system special suited to the characteristics of TK while accommodating the interests of TK holders. The nature and scope of proposed *sui generis* regime vary from scholar to scholar and from country to country. The system may take a form of IPRs or non IPRs *sui generis* regime or may be the combination of the two forms, and in

[203] *Id.*, Art. 7
[204] *Id.*, Art. 6(2)
[205] Nagoya Protocol, Art. 6
[206] WIPO-IGC Working Document, Art. 8
[207] Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection,* 7(2) J. INT'L ECO. L. 371, 376 (2004)

most cases ABS forms part of it. The *sui generis* system of protection, at its core, is the recognition or/and incorporation of customary laws.[208]

The fundamental problem underlying the debate on the *sui generis* system of protection is, whether it is better to put the national or international cart first, so as to effectively protect TK. While each country and scholar will come up with good reasons to answer this question, the undeniable fact is there is no simple solution to this dilemma.

Some countries and WIPO, advocate to test the effectiveness of national system first, in order to gain experience that makes it easier to determine what a workable international solution should look like.[209] Given the great variety of TK systems practiced in indigenous and traditional communities those in turn make up most of the world's cultural, intellectual and jurisprudential diversity; it would be vein to assume international system is a panacea to all problems raised by TK holders. Reflecting the difficulty, Dutfield has observed that it may become useless or inoperative due to the difficulty to accommodate diversity.[210]

Considering this may direct to opt the national *sui generis* system. The undeniable problem with having a national system, however, is that no matter how effective it may be at the domestic level, it would have no extra-territorial effect. Consequently, since in many cases the appropriation of TK is made by foreign companies, which eventually obtain IPRs protection abroad while TK holders would not be able to secure similar protection abroad, it leaves many

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[208] WIPO**,** *Elements of a Sui Generis System for the Protection of Traditional Knowledge*, Document prepared by the Secretariat to the third Session of the IGC, at Para. 42, WIPO Doc. WIPO/GRTKF/IC/3/8 (March 29, 2002); *see also*:Maui Solomon, *Strengthening Traditional Knowledge Systems and Customary Laws*, *in* PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS 155, 164 (S. Twarog and P. Kapoor, eds. 2004)

[209] WIPO/GRTKF/IC/3/8, *supra* note208, at 4[notes that , a 'top-down' or a pre-emptive approach to defining *sui generis* protection at international level is less likely to succeed if it is shaped without reference to the experience gained from operational national systems that provide practical models for functioning TK protection.]

[210] Graham Dutfield, *New Forms of Sui Generis Protection*, Paper Presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, at 34 (October 24-27, 2004) available at http://www.conabio.gob.mx/institucion/cooperacion_internacional/doctos/version_ingles.pdf [accessed on July 5, 2010] *"An international sui generis system may turn out to be useless or even dysfunctional. […] A legal system that works for a group inhabiting a valley in the Upper Amazon may be totally inappropriate for another group in Siberia or even in a neighboring valley. For a common international regime to provide effective international legal protection in foreign jurisdictions, a certain degree of harmonization would be necessary. And a harmonized system cannot easily accommodate diversity. The result may be a regime that is appropriate to no culture and is therefore useless."*

of the problems (especially '*biopiracy'*) unresolved, and exploitative behavior in other countries would go on as before.[211] Thus, any national system shall be supported by international enforcement machinery, if effective protection that can achieve its purpose is said to be effected. In this regard, Correa sees the relevance of private international law so that decisions regarding TK protection under a particular national law would become enforceable in other jurisdictions.[212]

Until the time international norm is established fully, other potential solutions are also proposed and sometimes employed by some countries. For instance, India has proposed for extra territorial application of *sui generis* regimes established on the national level, based on mutual recognition at the international level.[213] Thailand, applies the principle of reciprocity to the protection of TMK held by nationals of other states. That is, persons with nationality of other state who agree to permit persons with Thailand nationality to have the *sui generis* protection may seek protection in Thailand.[214] However, the effectiveness of reciprocity is questionable given the different priority states have on the protection of TK.

Initiatives have been made at the international, regional and national level to establish *sui generis* system of protection to TK. There is also regional *Sui generis* model laws and legislations, but not discussed in this chapter. The initiative made by the African Union (former OAU) and Andean community[215] are land mark examples of regional *sui generis* systems. The following sections, give an insight on three national *sui generis* legislations- India, Costa Rica and Thailand-[216] and the ongoing discussions in major international organizations.

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[211] *Id.*

[212] Correa, *supra* note 5, at 17

[213] Department of Commerce of India, *'Protecting traditional knowledge – The international dimension'*, prepared for the International Seminar on Systems of Protection of Traditional Knowledge Organised by the Department of Commerce, Government of India in Cooperation with UNCTAD, New Delhi, at 6-7 (April 3-5, 2002) available at http://www.unctad.org/trade_env/test1/meetings/delhi/background.doc [accessed on July 15, 2010]

[214] Art. 45 of Traditional Thai Intelligence Act

[215] The Common Regime on Access to genetic Resources of the Andean community, Decision 391 and the Common Intellectual Property of the Region of the Andean Community, Decision 486

[216] Selection of the countries whose experience is to be discussed is not made for granted. Rather, it is based on the criterions that can help to achieve an objective. Here the objective is to show different legal options that

3.4.1. *Selected National Experience*

I. India

Taking a lesson from the bad patents granted in different parts of the world based on TMK originated in India, Indian government took many positive and bold steps to protect TK. In this regard, different measures have been employed, *inter alia*, includes amendment to the patent act, enact new biodiversity legislation and documentation of TK.

To prevent patenting of Indian TK, new grounds of opposition and revocation regarding the prior art of TK was added to the patent act in the 2005 amendment. That is, the knowledge available within local and indigenous communities, irrespective of its form, will be treated as prior art.[217] Another amendment introduced to the patent act concerns disclosure. The amendment requires the patent applicant to disclose the genetic resource used and the origin of the genetic resource and sets it as a valid ground to oppose the patent.[218]

The development of TK Digital Library (TKDL) by the Indian government is another way of preventing illegitimate granting of patents on TK of India. TKDL is a database that compiles TMK available in the public domain, in five international languages so that patent examiners from all over the world can easily retrieve.[219] To make this a reality it is accompanied by Traditional Knowledge Resource Classification (TKRC) - an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval for patent examination.[220] In few states, there are also village wise Community Biodiversity Registers (CBRs) for documenting knowledge, innovations and practices at local level.[221]

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can be employed to protect TMK. In this vein, though every legal system has its own unique features there is a great deal of features shared by many jurisdictions.

[217] The Patents (Amendment) Act, 2005 No. 15 of 2005, Ministry of Law and Justice (Legislative Department), Govt. of India, New Delhi, (2005); Secs. 25(k) & 64 (q) *"[…] that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere*."

[218] *Id.*, Secs. 25(j) & 26 (j) stipulates the grounds of opposition where *"[…] that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention;*

[219] Available at http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng [accessed on May 20, 2010]

[220] Elizabeth Varkey, *Traditional Knowledge – The Changing Scenario In India*, 8 (2007) available at http://www.law.ed.ac.uk/ahrb/publications/online/varkey.htm [accessed on September 8, 2010]

[221] *Id.*, at 9

It is said elsewhere that mere documentation of TK, though deter patenting of TK may not lead to the sharing of benefits arising from the use of such knowledge, unless it is accompanied by other mechanisms for protecting the knowledge. But this is not the case for India; as stated previously, it is only accessed freely by patent examiners with non disclosure agreement and in any other cases supported by ABS legislation. To ensure that the holders of TK get the benefits arising from the use of TK, an enabling provision for protecting TK has been included in the 2002 Biodiversity Bill.[222] Section 36(5) of the bill provides for protection of the knowledge of local people relating to biodiversity through measures such as registration of such knowledge and development of a *sui generis* system. For ensuring equitable sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 stipulate that the approval of the National Biodiversity Authority (NBA) must be secured before the resources can be accessed. While granting approval, the NBA will impose terms and conditions that secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of IPR to research based on TK obtained from India needs to first obtain the approval of the NBA, which will impose benefit-sharing conditions. Section 18(4) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPR in any country outside India to any biological resource obtained from India or on knowledge associated with such a biological resource.

II. Costa Rica

Costa Rica is among the leading countries in taking legislative measures to protect TK by enacting Biodiversity law.[223] The law sets provisions aimed at protecting TK, regulating access to TK and securing benefit sharing arising out of the use of TK. The scope of TK covered by the law is limited to biodiversity related TK.[224] Unlike the generalizations that TK is collective, the law recognizes the possibility of TK held by individual, and covers all

[222] The Biological Diversity Act, 2002 No. 18 of 2003, Ministry of Law and Justice (Legislative Department), Govt. of India, New Delhi, (2003)
[223] Biodiversity law of the Republic of Costa Rica, Decree No. 7788 adopted by the Legislative Assembly of the Republic of Costa Rica in April 23rd of 1998 [here in after CRBL]
[224] *Id.*, Arts. 3 & 7(2)

'*knowledge, innovations and practices, be they traditional, individual or collective'*.[225] The modalities of protection incorporated under chapter V of this law are highlighted as follows.

With regard to access to biological resources and associated TK, it provides the legal requirements of access that includes the PIC[226] of TK holders[227] and approval of PIC by the National Commission for the Management of Biodiversity (CONAGEBIO)[228], access permit by the technical office of CONAGEBIO (technical office),[229] transfer of technology and equitable benefit sharing to be agreed during access permit.[230] The access permit is issued for a term of no more than three years and can be extended at the discretion of the Technical Office.[231] Such permits have several characteristics, among other things, includes that it is personal and cannot be transferred; materially limited to the authorized genetic or biochemical elements; and used only in the area or territory for which they have been specifically issued.[232] Such access permit only allows the activities agreed to be carried out, but not grant or delegate rights.[233] The benefit to be shared forms part of the PIC, and the technical office is entrusted to determine the amount and forms of benefits.[234]

Though there is no clear provision for consideration of customary law, it upholds the right of communities to oppose access to their resources or associated knowledge *'for cultural, spiritual, social, economic or other motives'*.[235] The law put exceptions by excluding the

[225] *Id.*, Art. 7(2)
[226] Prior informed consent is defined by Art. 7(9) as: *'Procedure through which the State, private owners or the local or indigenous communities, as the case may be, properly supplied with all the required information, allow access to their biological resources or to intangible components associated to them, under mutually agreed conditions.'*
[227] *Id.*, Art. 63(1)
[228] *Id.*, Art. 63(2)
[229] *Id.*, Art. 69
[230] *Id.*, Art. 63(3)
[231] *Id.*, Art. 70
[232] *Id.*, Art. 70
[233] *Id.*, Art. 71
[234] *Id.*, Art. 76 this provision also empowered the technical office to '*establish the obligation of the interested party to deposit up to ten percent (10%) of the research budget and up to fifty percent (50%) of the bonuses which it collects, in favour of the National System of Conservation Areas, the indigenous territory or the private owner providing access to the components.'*
[235] *Id.*, Art. 66

applicability of these rules to the exchange of knowledge among the indigenous people and local communities for non profit making purposes.[236]

More over, article 82 establishes community intellectual rights which read as:

> *The State expressly recognizes and protects, under the common denomination of sui generis community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemical's; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status.*

Details about the nature, scope and requirements of these rights are not addressed by the law. Rather, it leaves it to be determined by the technical office through participatory process of concerned communities.[237] Once this participatory process has taken place, the specific *sui generis* community intellectual rights for which the communities have requested protection will be inventoried keeping in mind the possibility that others may demand similar protection for TK with the same characteristics.[238] The recognition of these rights in the Registry of the Technical Office is voluntary and free of charge.[239] Such recognition must be made ex officio or at the request of the interested parties, without being subjected to any type of formality.[240] The existence of such recognition in the Registry will compel the Technical Office to refuse or to accept any intellectual rights on the same knowledge.[241]

When patent application is made for an invention involving genetic resources or associated knowledge, the respective authorities are obliged to consult the technical office before granting patent.[242] In addition, the applicant is required to provide the certificate of origin and

[236] *Id.*, Art. 4
[237] *Id.*, Art. 83
[238] *Id.*, Art. 84
[239] *Id.*
[240] *Id.*
[241] *Id.*
[242] *Id.*, Art. 80

PIC issued by the technical office. If justified opposition is made by the technical office, patent will not be granted.[243]

III. Thailand

Thailand has developed a special kind of *sui generis* regime that is specifically designed to protect and promote TMK i.e. '*Thai Traditional Medicinal Intelligence Act'*.[244] The act recognize a wide range of traditional Thai medicinal intelligence- Formulas on Traditional Thai Drug[245] [FTTD] and Texts on Traditional Thai Medicines[246] [TTTM]- and protects through *sui generis* form of IPR viz. Traditional Thai Medicinal Intellectual Property Rights [TTM-IPRs]. With regard to the nature and form of protection it distinguishes between three different categories of FTTD/TTTM.

1. The National FTTD/TTTM:[247] These are formulas/texts that are determined by the ministry of public health based on the significant benefit or special medical or public health value they have.[248] These national formulae/texts belong to the state and those who want to use and develop them for commercial purpose must obtain a license from the government.[249]
2. General FTTD/TTTM:[250] These are formulas/texts widely used or their IP protection has expired. Like the national ones these are also determined by the ministry of public health.[251] These formulas/texts belong to no one and can be freely used by anyone.[252]
3. Private FTTD/TTTM:[253] These are formulas/texts the owner can use freely and develop the same, once he has registered and acquire TTM-IPR. If third parties want to use,

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[243] *Id.*
[244] Thailand act on Protection and Promotion of Traditional Thai Medicinal Intelligence, B.E. 2542, 1999 [here in after Traditional Thai Intelligence Act or shortened TTIA]
[245] *Id.*, Secs. 3 Parag. 5 define FTTD as '*formula stated as the production process and ingredients which contain Thai traditional drugs, no matter what form the ingredients are*.' Parag. 4 of the same article define Thai traditional drugs as '*medicines obtained directly from herbs or derived from mixture, blended or transformed herbs, and also include Thai traditional drugs under laws on drugs*.'
[246] *Id.*, Sec. 3 Parag. 3 defines TTTM as *'[…] technical knowledge concerned with traditional Thai medicine which has been written or recorded in Thai books, palm leaf, stone inscription or other materials or that have not been recorded but passed from generation to generation*.'
[247] *Id.*, Sec. 16(1)
[248] *Id.*, Sec. 17
[249] *Id.*, Sec. 19
[250] *Id.*, Sec. 16(2)
[251] *Id.*, Sec. 18
[252] WHO, Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine Bangkok, Thailand, 6–8 December 2000, at 19, WHO Doc. WHO/EDM/TRM/2001.1 (2001)
[253] TTIA, Sec. 16(3)

they must obtain permission and a license from the owner.[254] Every Thailand citizen who is[255] inventor/improver/developer/inheritor of the FTTD/TTTM can apply for registration to acquire TTM-IPR on their formulas/texts.[256] The conditions that are considered in the process of granting TTM-IPRs of this kind are not as strong as those required in traditional IPRs. In this regard, the authority entrusted to register TTM-IPR has the power to reject the application if it is of the opinion that: the claimed FTTD/TTTM belongs to the national or general FTTD/TTTM; it '*has been developed on non medical basis like the use of extracts of plants, animals or micro organisms that have not be obtained from natural extracts or the transformation that is not considered rough transformation*'.[257]

The act follows the first to file approach in order to solve disputes of ownership over knowledge that has been hold by more than one person. In other words, if separate application for protection of IPRs by different persons is made on the same subject, the person who forwarded the application first has the right to register and acquire IPRs.[258] Joint ownership is also possible in case where separate application for registration on the same knowledge is made by different persons.[259]

The right granted on the registered personal FTTD/TTTM is patent-like exclusive rights albeit the long time protection that remains in force throughout the life of the owner and subsist for a further period of fifty years from the date the right holder dies.[260] The right is said to be exclusive in a sense that the right holder have the sole ownership right over the production, research, distribution, improvement or development of the registered FTTD/TTTM.[261]

The right granted is not absolute to the extent of forbidding any use of the protected formula/text. It would rather legally possible to freely use all three types of formulae/texts

[254] Cumulative Reading of TTIA Secs. 34 & 36
[255] Persons with nationality of other nations may seek registration of IPR protection on the local TM in their country based on the principle of reciprocity i.e. if his home country agrees to permit Thailand nationals to have protection of IPR on traditional Thai medicine. *See*: Sec. 43 of TTIA
[256] *Id.*, Sec. 21
[257] *Id.*, Sec. 22
[258] *Id.*, Sec. 26
[259] *Id.*
[260] *Id.*, Sec. 33
[261] *Id.*, Sec. Chapeau of Art. 34

domestically by traditional healers or Thai communities in limited quantities.[262] It further puts limitations to the exclusive rights given to the right holder of personal formulae/text. That is, section 34 of the act excludes the applicability of the exclusive rights, provided that it is line with the rules and desertion of the ministry of public health.[263] Furthermore, the registrar is empowered to revoke the right granted to individuals if the right holder misuses his right against the public order or good moral.[264]

Promotion and securing protection is not the only objective of the act. The law also provides for measures aimed at the conservation and sustainable utilization of the medicinal plants, especially those at high risk of extinction.[265] Different administrative and judicial mechanisms are put in place so as to enforce the act. Civil liabilities and criminal sanctions are also provided for in case of infringement of the rules and rights incorporated under the act.[266]

3.4.2. Initiatives in International Organizations

The issue of protection of TK is debated in a wide range of international fora including WTO, WIPO, CBD, FAO, WHO, ILO to name a few. Recognition of TK in international soft laws is not something new for UN and its specialized agencies, especially, in the field of international environmental law. The focus of discussion here, however, is the major international organizations hosting contentious issues and ardent debates relating to protection of TK/TMK. Thus, following will be initiatives of four international organizations- WTO, WIPO, CBD and WHO- actively involved in the protection of TK/TMK.

I. WTO

TRIPS- one of the WTO single undertaking agreements directly related and relevant to TK- is silent on TK. It makes no reference to the CBD that comes in to force two years before it. Sponsored by developing countries TK and the relationship between TRIPS and CBD emerged in the WTO forum. Accordingly, at the fourth meeting of the WTO ministerial

[262] TTIA, Secs. 18, 19 & 34(3)
[263] *Id.*, Sec. 34 These are: Acts to the benefit of studies, findings, tests or research; Production of drugs for household use; Production of drugs by state hospitals or government or state agencies, for use in state hospitals; or Use of TTTM for benefits in treatment of patients in state hospitals.
[264] *Id.*, Secs. 37(1) & 41
[265] *Id.*, Sec. 44-65
[266] *Id.*, Sec. 77-82

conference which took place in Doha in 2001, a ministerial declaration was adopted according to which the WTO member states instructed:

> *the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore*[267].

Since then TK has become an especially important element of debate in WTO. Different proposals have been made to the protection of TK both defensively and offensively, *inter alia*, include:

- A provision for a *sui generis* protection of TK to be included in the TRIPS agreement.[268]
- A provision that required patent applicants for inventions that use TK to disclose the origin or source of TK, prior informed consent of the TK holders or competent authority in the country of origin, and evidence of benefit sharing.[269]

These are the proposals mainly sponsored by developing countries. In principle, developed countries agree on the need to protect TK, but they oppose the above proposals by providing other options. The suggestions that have been forwarded by developed countries are either the one that are proved to be ineffective or technically designed to shift the agenda from the WTO round table. For instance, Australia proposed to use the existing IPRs[270] while USA argue that the best way of addressing the issue of TK is through bilateral agreements and other national legislative measures and refused the introduction of international *sui generis* system.[271] EU is

[267] Doha Declaration, at Para. 19
[268] *See e.g.*, Communication from Brazil, *Review of Article 27.3(b),* WTO Doc. IP/C/W/228 (2000)
[269] The African Group submission, *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, WTO Doc. IP/C/W/404 (2003)
[270] *See e.g.*, Communication from Australia: *Review of Article 27.3(b),* WTO Doc. IP/C/W/310 (2001)
[271] *See e.g.*, United States submission relating to Article 27.3(b), *Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore,* WTO Doc. IP/C/W/434 (2004)

in the middle of the polarities. But, when we scrutinize EU's approach- voluntary disclosure[272]- it tends to favor ineffective mode of international protection.

Still the negotiation and debate remain intact in which each country come up with its own proposal. The only consensus that has been achieved is that there is no consensus. Therefore, it is not the right time to predict the direction of the negotiation.

II. WIPO

WIPO is one of the grand fora relating to TK. It began its work on TK-related subject matter in 1978, when it initiated discussions on the *sui generis* protection of expressions of folklore in collaboration with the United Nations Educational, Scientific and Cultural Organization (UNESCO). This work resulted in 1982 in the adoption of "*Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions"*.[273] However, this work is not concerned with TK stricto sensu. Rather it is limited to the expression of TK.

In 1998, WIPO began a new set of activities designed to explore the IP aspects of the protection of TK. In 2000, WIPO-IGC was established as a forum for discussions among Member States on IP issues arising in the context of (i) access to genetic resources and benefit sharing; (ii) protection of TK, whether or not associated with those resources; and (iii) protection of expressions of folklore.[274]

Since its inception the WIPO-IGC conducted number of important and promising tasks aimed at clarifying the subject matter of TK and analyzing different options for the protection of TK. To that end it developed a series of studies that includes surveys of national experiences with protection of TK. Sixteen sessions have been held so far and seventeenth session was

[272] *See e.g.,* Submission by European Communities and member States, *Review of Article 27.3(B) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/383 (2002)

[273] WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions, done in 1982

[274] WIPO, *Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, Decision of The Twenty-Sixth Session of the General Assembly, WIPO Doc. WO/GA/26/6 (August 25, 2000)

scheduled for December 2010. In the last session that took place in Geneva from May 3-7, the IGC prepared a working document. [*See:* Section 3.3]

Like the polarized views and debates in Doha round of WTO, the discussion on the protection of TK in the IGC is also characterized by intense disagreement between the north and the south. This can be inferred from the WIPO-IGC draft working document, which is full of two forward slashes' (//), struck through and underlined words and phrases to indicate that more than one proposals have been made, states has proposed to be deleted and insertions and additions are proposed, respectively.

No matter what the final result of the IGC it may be, it is hard to deny the positive and promising activities carried out by WIPO. For instance, it expanded minimum documentation that should be taken into account during an international search to include TK related information resources.[275]

III. CBD

As stated earlier, the CBD verbally recognizes TK and calls for the protection of it. Besides it also establish two working groups related to TK. The adoption of the Bonn guidelines and the Nagoya protocol on ABS, which are the out come of the ABS-WG are undeniably a land mark progress. Since the works undertaken by ABS-WG are discussed in the section dealing with benefit sharing, there is no need to duplicate the section here. Rather, this section is devoted to give an insight on other working group of the CBD relevant to TK protection. This is, the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions (WG-8(j)), established by COP-4 in 1998.[276]

The WG-8(j) has been serving as an important forum to discuss and formulate laws intended to protect TK. Since the time of its inception it has made tremendous efforts so as to have either mandatory agreements or voluntary guidelines in different aspects relevant to the implementation of Article 8(j) and other provisions related to TK. Among the tasks of this working group, development of a code of ethical conduct intended to be used as a guidance in

[275] WIPO Publication No. 920(E), *supra* note 30, at 29
[276] Report of the Fourth Meeting of the Conference of the Parties to the CBD, UNEP, Annex I, at 111, UN. Doc. UNEP/CBD/COP/4/27 (1998)

activities and interactions with indigenous and local communities, with the aim of promoting respect, preservation and maintenance of TK, is principally important programmes that makes it unique from other international fora.[277]

Other important mandates of the working group are: development of *sui generis* system for the protection of TK[278] and explore the possibility of developing technical guidelines for recording and documenting TK and to analyze the potential threats of documentation to the rights of the holders of TK.[279] The working group is the forum in which the TRIPS and IPRs are openly debated and critiqued since it has a mandate extended to asses IPR instruments that may have implications on the protection of TK with a view to identifying synergies between IPR instruments and the CBD.[280] Discussions in each forum of the CBD are based on participation of indigenous and local communities. This is an important feature of the work since it would accommodate the interests of TK holders, to the extent possible.

Despite striking efforts and progress that have been done yet, the CBD is not free from drawbacks. The primary shortcoming of this forum is the absence of effective dispute resolution mechanism to enforce the agreements reached by the contracting parties. Next to that, CBD being a biodiversity agreement is more concerned with conservation of biological resources. That is why its work on TK is limited to the knowledge only associated with genetic resources. Furthermore, it may be difficult to envisage CBD, which still does not include US as a full member, ever adopt a *sui generis* system that would require members to harmonize their IPR systems with their CBD related obligation to protect TK. Nevertheless, the CBD is the principal international organization to recognize TK in verbatim obligatory provisions, and also to take a positive progress to the full implementation of its provisions related to protection of TK and benefit sharing.

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[277] Decision of the Ninth of the Conference of the Parties to the CBD, UNEP, at 70 UN Doc. UNEP/CBD/COP/9/29 (2008)
[278] Report of the Fifth Meeting of the Conference of the Parties to the CBD, UNEP, Annex III, at 145, UN Doc. UNEP/CBD/COP/5/23 (2000)
[279] UNEP/CBD/COP/9/29, *supra* note 254, at 65
[280] UNEP/CBD/COP/5/23, *supra* note 255

IV. WHO

WHO's involvement in TK relates to the organization's work on TM through its TM programme.[281] As such, WHO is concerned to specific form of TK- TMK. In fact, its engagement in TM is not primarily aimed at protection of TMK, per se. Rather, it's principal objectives are to provide normative and country programme support so that states can integrate TM in to their national health care programmes; to ensure appropriate, safe and effective use of TM and increase the availability and affordability of TM, particular emphasis given to poor countries and their poor inhabitants.[282] This action is essentially crucial to give recognition to TMK and its holders by building confidence on its safety and efficacy. In doing so, protection and preservation of TMK is taken as a strategy.[283] Accordingly, WHO help countries to develop strategies to protect TMK. It also organizes and host different sessions and workshops on the protection of TMK and serves as a forum to create and improve awareness and capacity building.[284] Generally, even though it is not directly targeting protection in a strict sense, its involvement to ensure accessibility, affordability, efficacy, safety and rational use of TM and incidental discussions on protection of TMK is pioneer initiative from the unexplored angle; so that TMK will have concrete foundation backed by support from the majority of the public and the government.

3.5. Conflicting Interests

Internationally, developing countries support the protection of TK through IP type of protection that gives exclusive right to the holders of the knowledge. Conversely, developed countries are not in favor of this approach,[285] possibly due to the fact that multinational

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[281] For detailed discussion on WHO TM programme *see* generally: Akerele O., *WHO's traditional medicine programme: progress and perspectives*, 38(2) WHO CHRONICLE,76-81 (1984)

[282] WHO TM Strategy, *supra* note 58, at 43-45

[283] *Id.*, at 46

[284] For instance, WHO Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine held in Bangkok in December 2000 [for the effective promotion of TMK, the Workshop produced a list of recommendations including the following: Ways and means need to be devised and customary laws strengthened for the protection of TMK of the community from biopiracy; TK which is in the public domain needs to be documented in the form of TK digital libraries, and such information needs to be exchanged and disseminated through systems or mechanisms relating to IPRs; Governments should develop and use all possible systems including the *sui generis* model for TM protection and equitable benefit sharing. Countries should develop guidelines or laws and enforce them to ensure benefit sharing with the community for commercial use of TK; Efforts should be made to utilize the flexibility provided under the TRIPS Agreement with a view to promoting easy access to TM for the health care needs of developing countries.]

[285] Dwyer, *supra* note 108, at 234

pharmaceutical companies from these countries are the greatest poachers of TK from their developing counterparts. It has been argued elsewhere that the existing IP system protect knowledge that was thought to exist with in the developed world, but not TK which is the intellectual goods of developing countries.[286] Reflecting this, a commentator asserted that:

> *The desire for an international regime to protect traditional knowledge may be part of a negotiating strategy in response to developed country demands for stronger intellectual property rights. The trade-off would be that the developed countries would be required to protect traditional knowledge in exchange for enhanced intellectual property laws.*[287]

The issue of protection of TK is often framed as a North-South confrontation because of the fact that the developed world is interested in higher levels of IPRs, while the developing world interested in the protection of TK.[288]

Developing countries perceive that IPRs does not further their interest and enhanced IP law as ill suited to their level of economic development and sought more relaxed IP standards than those which were ultimately implemented in TRIPS.[289] Had it not been part of a single undertaking of WTO agreements and threatened by the big elephants, developing countries will never lend themselves to the TRIPS.[290] That is why they consider it as an imposition by developed countries.[291]

Considering these facts, it seems dubious why developing countries wish for the IP type exclusive protection to TK. Especially, in the field of medicine the opposition to IPRs is more sever since it is related to human rights and access to drugs. Literatures are full of studies seeking to demonstrate the negative effect of IPRs to the health needs of the great majority of

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[286] *Id.*, at 233
[287] OseiTutu, *supra* note 102, at 39
[288] *Id.*
[289] Arewa, *supra* note 87, at 168; *See also:* Getachew Mengistie, *The Impact of the International Patent System on Developing Countries*, 23 J. ETH. L 161-219 (2009)
[290] Dwyer, *supra* note 108, at 238-239 (noting unilateral threat of US sanction under section 301as the reason why developing countries accept TRIPS)
[291] Dutfield, *supra* note 34, at 238

the population in the developing world.[292] It is fact that exclusive rights will increase the cost of a product.[293] Accordingly, giving exclusive right to the holders of TMK means to scale TM beyond the reach of the poor which is otherwise the only affordable and accessible treatment. Therefore, granting exclusive right to TMK should be considered curiously in line with the public health policy.

Dutfield reflects skeptic view that developing countries are simply using the issue either to justify implementing an agreement they dislike as slowly as they can get or to obtain non TRIPS related trade concessions, notably in agriculture.[294] It seems, *prima facie*, a good bargaining strategy to the developing countries in the international diplomacy. That is, if they are likely to get major concessions in negotiations in agriculture by softening their positions on TK issues then it makes sense for them to soften their stand. The problem, however, is that the grouping in agricultural negotiation is much more complicated than north-south divide, since liberalization of international trade in the field of agriculture will goes against the interest of least developing and net food importer countries.[295] Therefore, coalition of all developing countries so as to use TK as a bargaining issue in agricultural negotiation is unlikely to happen.

The fundamental fact that one can peruse from the above discussion is that protection of TK, particularly TMK, is at a cross road of conflicting interest; Viz. north-south divide, the paradox of IP type protection vs. public health policy and varying interest of the south in international trade, to name a few.

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[292] For example for discussion on the oppositions on pharmaceutical patents *See*: Susan K. Sell, *Post TRIPS Developments: the Tension between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193, 208-216 (2001)

[293] Philippe Cullet, *Patents Bill, TRIPS and Right to Health*, International Environmental Law Research Centre 36(43) ECONOMIC AND POLITICAL WEEKLY, October 27, 2001, at 1

[294] Dutfield, *supra* note 34, at 239

[295] Srinivas, *supra* note 175, at 109

CHAPETER FOUR

4. PROTECTION OF TMK IN EHTIOPIA

4.1. *Introduction to TK/TMK Practices in Ethiopia*

Ethiopia is socio-culturally diverse nation with more than 80 ethnic groups. Each ethnic group having its own culture, tradition and innovative practices, is rich in TK of different kind. The increasing number of music albums released accommodating traditional songs and dances in the previous few years, and their wider acceptance and recognition is the best evidence of the country's richness in folklore songs and traditional cultural expressions.

The country is also epitomized as one of the leading rich biodiversity countries of the globe and home for many endemic genetic resources.[296] Several reasons can be cited to explain the country's richness in biological diversity, among other things, the socio-cultural diversity of the population is the one. Despite the variance one might get in several study findings estimating the total number of medicinal plants found in the country, the fundamental fact agreed by all, is that Ethiopia is home to substantial number of resources that have been used and have the potential to be used as medicine. In this regard Jansen asserts that almost all plants of the Ethiopian flora are used somewhere somehow for medical purposes so as to reflect the abundance of TMK available in Ethiopia.[297]

In Ethiopia, TM has been used to combat human and livestock ailments and to prevent pests and vectors, since time of immemorial.[298] Due to its long period of practice and existence, TM has become an integral part of the culture of Ethiopian societies.[299] Even at the present time, with factors attributed to its accessibility, affordability and cultural-entrenchment, TM serves

[296] Endashaw Bekele, *Study on Actual Situation of Medicinal Plants in Ethiopia*, Study funded by Japan Association for International Collaboration of Agriculture and Forestry (JAICAF) 17 (2007) available at http://www.endashaw.com [Accessed on June 5, 2010]

[297] Jansen P.C.M. *Spices, Condiments and Medicinal Plants in Ethiopia, Their Taxonomy and Agricultural Significance*, College of Agriculture, Addis Ababa (1981) *as cited in:* Endashaw, at 18

[298] Alevtina Gall & Zerihun Shenkute, *Ethiopian Traditional and Herbal Medications and their Interactions with Conventional Drugs*, (2009) Available at http://ethnomed.org/clinical/pharmacy/ethiopian-herb-drug-interactions.html [Accessed on June 5, 2010] For brief discussion on history of TM in Ethiopia, *See generally*: RICHARD PANKRUST, AN INTRODUCTION TO THE MEDICINAL HISTORY OF ETHIOPIA, (1990); and, Richard Pankrust, *An Historical Examination of Traditional Ethiopian Medicine and Surgery*, 3 ETH. MED. J 157- 172 (1965)

[299] Gidey Yirga, *Ethnobotanical Study of Medicinal Plants in and Around Alamata, Southern Tigray, Northern Ethiopia*, 2(5) CURR. RES. J. BIOL. SCI. 338, 338 (2010)

as preferred means of medication for significant number of the population, to satisfy their basic health needs. Intriguingly, according to WHO, Ethiopia is at the apex in percentage of the population using TM to meet their primary health needs- a figure that approaches to 90 *percent*.[300]

Given the fact that TM is embedded in the cultural and religious belief systems, the knowledge and practices of TM are as diverse as the culture it self.[301] That is, peoples in different location with different religious, linguistic and cultural backgrounds have their own specific TMK. In some cases the knowledge is restricted only to members of each ethnic group, while part of the knowledge has gradually entered wide circulation in the country; and hence, shared and practiced by more than one ethnic group or throughout the country.[302] Though there is widely known TMK, the great deal of the knowledge is reported to be unevenly distributed among members of the community.[303] To put it differently, TMK holders significantly vary viz. a single community, more than one community, group of persons (in most cases members of a clan or a family) or single or different individuals. As such owing to the diversity of TM practices, it is difficult to particularly define the basic categories of TMPs.. For instance, Endashaw tempted to elucidate practitioners into herbalists, bone setters, traditional birth attendants, spiritual healers, diviners and magicians as a general approach to classify them.[304]

The transfer of TMK itself exhibits a peculiar feature where basically it is conveyed from one generation to the next through words of mouth with certain cultural and spiritual procedures.[305] Of course, remark must also be sought to those ancient traditional medical texts that contain reference about medicinal plants including their applications and uses.[306] However, the availability or accessibility of such documents is in scant ways. In addition, more recently ethno-botanical and relared publications could also be considered as modes of

[300] WHO, '*Traditional Medicine –Growing Needs and Potential'*, WHO Policy Perspectives on Medicines No. 2, 1(May 2002)
[301] Kebede, et al., *supra* note 65, at 128
[302] Endashaw, *supra* note296, at 3
[303] *Id.*, at 29
[304] *Id.*, at 21
[305] Kebede, et al, *supra* note 65, at 128
[306] Fekadu Fullas, *The Role of Indigenous Medicinal Plants in Ethiopian Healthcare* (2005) available at http://www.hollerafrica.com/showArticle.php?artId=217&catId=1 [Accessed on June 5, 2010]

knowledge transfer or preservation.[307] But, considering the countries immense flora and socio cultural diversity, these documents are of very limited coverage as TMK systems vary across culture.[308]

4.2. *TMK's role to the National Economy and Health Care System*

As said earlier, the great majority of Ethiopian population uses TM to meet their primary health care needs. This clearly implies the significant role of TM and its associated knowledge to the primary health care system is undeniable, no matter how it is not formally integrated in to the national health care system. [*See*: section 4.6]

Although it is found to be difficult to identify the actual expenditure allotted on TM treatment, estimates have been made on the total expenditure on TM and its associated treatment. The study undertaken by Mender et al. revealed that TM trade value in the year 2005 was estimated to be two billion Ethiopian Birr (ETB) (some 8 *percent* of the total budget of the fiscal year), and the healing service provided by healers is estimated to be around 1.6 billion ETB.[309] Furthermore, the value of medicinal plants both traded and non-traded was 423 million ETB, which constitutes 42 *percent* of the national estimated health spending on pharmaceutical products.[310] This is a significant saving in terms of foreign currency. The study shows that TM contributes an additional two billion ETB to the GDP via the informal trade and the industry provides some 346,000 income earning opportunities associated with the trade.[311] Generally, this figure shows that in addition to the health care advantage which the country and its people benefits, the economy as a whole also benefits substantially.

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[307] *Id.*

[308] Interview with Ato Kebu Beletie, an Ethno Biologist in IBCR Genetic Resource Transfer and Regulation Directorate, Addis Ababa (September 25, 2010)

[309] Mender M., et al., Marketing of Medicinal Plants in Ethiopia: A Survey of The Trade in Medicinal Plants. A research report prepared for Sustainable Use of Medicinal Plants Project, Institute of Biodiversity Conservation, Addis Ababa, 221(2006) *as cited in* Belachew Wassihun, *National Economic Value of the Unexploited Traditional Medicinal Plants, Biodiversity Newsletter*, (2008) available at http://www.ibc-et.org/Newsletter/tiki-read_article.php?articleId=4&page=2 [Accessed on June 15, 2010]

[310] *Id.*

[311] *Id.*

4.3. *Threats to the Environment and TMK*

Most of TMs are derived from knowledge about the use of plants, and people satisfy their demand of TM by indiscriminate unwise bulk harvesting of plants.[312] As a result, while there is a growing demands for such medicinal plants, many plant species have become instinct and some are endangered.[313] The loss of medicinal plants has a serious environmental and socio-economic implication, given the number of consumers and their reliance on medicinal plants. The loss might also have deleterious consequence on the TMK held by both individuals and the community. Besides, it would ultimately entail adverse effects upon TMK, particularly owing to the oral transmission of the knowledge, since unavailability of the plants may lead to impracticability and hence total disappearance of the knowledge. Therefore, conservation of natural resource is two-edge sword, meaning that natural resource conservation is not only for the sake of the environment but also to salvage the knowledge associated with it from disappearance. Needless to say, the younger generations have other ambitions priorities than to acquire/inherit TMK.[314] This is a great concern to TMK system as it will deeply dig the grave of this precious resource in collaboration with the above said threats.

4.4. *Expectations of TM Practitioners (TMPs)*

There is insufficient information on the actual contents of TMK found and who really holds them, an economic appraisal of the value of TMK, customary laws available to protect TMK and other basic issues that needs to be considered in formulating appropriate legislative measures in order to protect TMK. There is a general understanding that TMPs are the best source of information about TMK. Recognizing this fact, efforts have been made to explore the attitude of TMPs to their knowledge and their needs and expectation regarding the protection of TMK. It is not imaginable to do this task primarily based on primary data due to financial and time limitation. Let alone with in this limited time space and financial problem, big projects conducted by grant of relatively huge fund fail to reach final representative conclusion. What has been done in this thesis is to assess studies conducted in relation to the subject matter at hand, and to analyze information gathered personally through interview with TMPs. The big challenge faced was that there is no TMPs association functioning that can

[312] Interview with Ato Kebu Beletie, *supra* note 308
[313] *Id.*
[314] Endashaw, *supra* note 296, at 41

ease collection of representative information, relatively. The Ethiopian National Traditional Medicine Preparation and Study Association (ENTMPSA) was the only national association of TMPs but judicially dissolved before two years. But, its position was assessed by examining decision passed and letters sent by the association at the time it was operational. Some TMPs who were members and key participants of the former association and now struggling to rekindle it are also interviewed. Furthermore, individuals who had been involved in gathering data for studies related with the subject matter being dealt are also communicated.

Studies show that significant majority of TMPs consider their TMK as private property.[315] But they fail to indicate what they consider private property is the one they believe to be held by only them or also shared by others. This is because of the fact that many key informants in different studies think their knowledge is either mentored or known by others.[316] This issue needs comprehensive exploration through further study to unpack the mysteries behind it. However, preliminary reflection one would possibly make concerning the private nature of the knowledge is its secrecy. There are considerable evidences to support this assertion. For instance, the same studies revealed that certain types of knowledge are held as secret by practitioners.[317] The TMPs interviewed by the writer of this paper also affirm that TMK is secret due to different personal economic and social interest attached to it and other cultural considerations.[318]

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[315] Imiru Tamirat, *Protection of Traditional Medicinal Knowledge in Ethiopia*, concept paper prepared for IPR Policy Guidelines for the Protection of TMK Project under the Conservation and Sustainable Use of Medicinal Plants Project in Ethiopia, Financed by the International Development Fund (IDA) and The Global Environment Facility (GEF) 23 (November 2000) [here in after Imiru (concept paper)] [To identify the needs and expectations of TMK holders the study include survey in Addis Ababa and Bale. The concept paper noted that 72.7 *percent* of the participants respond that they view their knowledge as private property]; Tibebu Solomon, *Assessment of Possible Intellectual Property Protection Options of Traditional Knowledge Systems in Ethiopia: Special Reference to Herbal Medicine*, Progress Report for the Period May-July 2010 for Study Being Carried Out under a Research Support by African Technology Policy Studies Network (ATPSN), 4 (2010) [here in after Tibebu (Progress Report)] [The study is being carried out collecting data's from 10 different parts of Ethiopia.]

[316] Imiru (concept paper) at 23; and, Tibebu (Progress Report) at 4-5

[317] Imiru (concept paper) at 35; and, Tibebu (Progress Report) at 5

[318] Interview with Bekele Daba, Traditional medical practitioner and owner of Bekele and His Family Traditional Medical Center, Lege Tafo (October 17, 2010); Interview with Haji Muhammad Awol, Traditional medical practitioner and owner of Haji Muhammad Awol Traditional Medical Center, Addis Ababa (October 10, 2010); and, Interview with M/Geta Afework Getahun, Traditional Medical practitioner and owner of Kokeb Birhan Traditional Medical Center, Addis Ababa (October 14, 2010) [all three were members of the former ENTMPSA, while the later two also involve in the effort to rekindle the association]

According to well known community knowledge advocate Dr. Tewoldebirhan, the secrecy of knowledge doesn't amounts to private ownership.[319] It is only wise system of the community which arranged some of the medicinal application of plants to be practiced and held secret by limited specialized practitioners.[320] Meaning, if some medicine is thought to have no side effect, it is left to the whole member of the community so that they can all practice it; whereas in cases when there is risk in use of TM by the large member of the community and hence needs specialization, it is entrusted to individuals to practice and held it secret on behalf of the community.[321] Therefore, he concludes that there is no private ownership in local communities and all TMK belongs to the community.[322] Whilst this may be true in some cases, it is hardly possible to make generalization. For instance, one of the TMPs interviewed- M/Geta Afework- though recognize his responsibility to the community at large, reflect economic interest of keeping the knowledge secret, literally he said '*if I disclose, I'm not necessary to continue as practitioner. Therefore, I and my family depend on the income derived from it are going to loose our basic means of livelihood.*'[323]

In relation to their willingness to disclose their knowledge, the data's available underline that most of them are volunteer to disclose to the government if mechanisms are put in place to make them beneficiary.[324] The decision of ENTMPSA and letter sent by it to the Ethiopia Intellectual Property Office (EIPO) also demonstrates the same claim.[325] TMPs interviewed also equivocally respond that they are volunteer as long as it doesn't goes against their interest and do not hurt them.[326] Whether they will respond in the same positive way in practice is

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[319] Telephone Interview With Dr. Tewoldebirhan G/Egziabher, General Manager of Ethiopian Environmental Protection Authority, Addis Ababa (November 1, 2010) [Dr. Tewoldebirhan was one of the principal architect of the African Model law]

[320] *Id.*

[321] *Id.*

[322] *Id.*

[323] Interview with M/Geta Afework Getahun, *supra* note 318 [original Amharic, my own translation]

[324] Imiru (concept paper), *supra* note 315, at 23; and, Tibebu (Progress Report), *supra* note 315, at 5

[325] **የኢትዮጵያ ብሔራዊ ባህላዊ መድኃኒት ቅመማና ሕክምና ጥናት ማኅበር አባላት የባህላዊ መድኃኒት ዕዉቀት ሽግግር ናሙና ስምምነት በተመለከተ ያደረጉት ስብሰባ ቃለጉባኤ እና ዉሳኔ** (**አዲስ አበባ** 1998); and, **ከኢትዮጵያ ብሔራዊ ባህላዊ መድኃኒት ቅመማና ሕክምና ጥናት ማኅበር በቀን** 03/04/98 **፣ በሳይንስና ቴክኖሎጂ ኮሚሽን ለአእምሯዊ ንብረት ጽ/ቤት በቁጥር ባ/መ/ማ**/73/98 **የተላከ ደብዳቤ** (**አዲስ አበባ** 1998) [All the documents are concerning model TMK transfer agreement developed by IPR policy guidelines for the protection of TMK project. The members of the association unanimously approve the model TMK transfer agreement believing that it is to the best interest of them and have no negative effect. However, they criticize the adoption of the model agreement without participation of at least representatives of the association.]

[326] Interview with M/Geta Afework, Haji Muhammad and Bekele, *supra* note 318

questionable, as there are facts that substantiate to the contrary. For instance, an initiative has been tried by the Ethiopia Nutrition and Drug Research Institute to further develop TMs by research in collaboration with TMPs.[327] To that end a memorandum of understanding was concluded between the institute and some practitioners.[328] When the institute began a move to accomplish the agreement, however, the TMPs failed to repeat their prior expressed commitments in which no one approaches to disclose his knowledge.[329] Different logical reasons can be raised to justify their action. The lesson Ato Wondwessen notes at the time when he collects data around Bale area (Southern Ethiopia in Oromia Regional state) is more plausible to mention here.[330] That is, he appreciates the over ambitious expectation of TMK holders about their knowledge.[331] It is mainly due to the fact that misleading information some NGOs propagates alleging it worth millions of dollars and advocate not to disclose it in any ways as every body including the government is ready to cheat them.[332] According to him, those who know single TM and do not base their livelihood on it, however, are more likely to share their knowledge albeit fear of social recognition.[333] One thing that should not be disregarded is the existence of cultural belief deterring any dissemination of TMK i.e. the belief that the medicine will loose its power and thus will not work if disseminated.

Concerning protection of TMK, TMPs interviewed underscore on two fundamental issues. The first is the need to recognize it and its value.[334] Secondly, degradation of medicinal plants is in the way to accelerate the loss of TMK, therefore, there is a pressing need for recovering valuable medicinal plants.[335]

There is lack of awareness on part of TMPs on the potential legal mechanisms available to protect TK. They stressed on recognition of their practice by the government and/or the

[327] Interview with Dr. Getachew Addis, In Ethiopian Health and Nutrition Research Institute (EHNRI) Modern and Traditional Drug Research Directorate Director, Addis Ababa (October 22, 2010)
[328] *Id.*
[329] *Id.*
[330] Interview with Ato Wondwessen Belete, In EIPO Patent Protection and Technology Transfer Development Process Director, Addis Ababa (October 15, 2010)
[331] *Id.*
[332] *Id.*
[333] *Id.*
[334] Interview with M/Geta Afework, Haji Muhammad and Bekele, *supra* note 318
[335] *Id.*

monetary benefit derived from utilization of the knowledge. In relation to proprietary right, no one goes beyond protection through secrecy and customary norms.

4.5. *What ought to be Secured from Protection of TMK?*

It is believed that protection of TK appears in the international agenda and national legal systems after annoying claims of misappropriation of TMK by pharmaceutical companies through patents.[336] However, prevention of misappropriation is the immediate cause and only one of the many objectives. As mentioned in the previous chapter, there are number of policy objectives that sought to be achieved from protection of TMK. The overall objective of protecting TMK would be to recognize the value, preserve, encourage and promote the use of TMK, taking in to account the needs and expectations of TMK holders and the communities who benefit from its use. [For further discussion *see*: Chapter 3.1]

Nonetheless, given the great variety of TMK systems and different policy priorities of different states, the primary objectives that states assume from protection of TMK will inevitably differ. For instance, currently, the objective Ethiopia and China needs to secure from protection of TMK will never be one and the same, though there exists some to share. It is mainly because of the fact that while China's TMK is well documented, developed and integrated to modern health care system and even educational curricula, and hence it has gained much popularity through out the world;[337] in Ethiopia no positive progress has been made to any of these tasks. [See: next section] In addition, the technological capacity of Ethiopia and China is apparently different that in turn has enormous impact in designing policies in every sphere.

Therefore, protection of TMK in Ethiopia should have to consider the current situations of the country in general and the special features of TMK systems available in particular. These, among other things, include: the interest of the majority of the population mainly depends on TM and associated knowledge; the level of development of TMK and its integration to the modern health care system; economical and technological capacity of the country to carry out research and development.

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[336] *Id.*

[337] *See generally*: Jerry I. H. Hsiao, *Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan*, 10 J. WORD. INTL'L PROP. 1–21 (2007)

In due course, the legal regime of protecting TMK needs to balance, the economic interests of TMK holders from the wide use and commercialization of their TMK, in the one hand, and, promote research and development on TMK that attracts foreign researchers while ensuring the accessibility and affordability of TM to the majority of the population, on the other hand.

4.6. *Preliminary Consideration of Policies and Laws Relevant to TMK*

4.6.1. *The Criminal Code*

The wide and long practice of TM and its culturally embedded acceptability will not necessarily guarantee its safety and efficacy. Thus, the safety and efficacy of TM practices remains sensitive public health issue, which needs some sort of regulation. To make matters worse, it was reported that TMK to some extent employs superstitious beliefs and harmful practices.[338] In this regard, the criminal code of Ethiopia does not tolerate traditional harmful practices and some superstitious practices as it provide guidelines to practice TM. In its preface the code affirms that the constitution guarantees respect for the culture of the peoples.[339] However, it argues that the constitution '*does not buttress up those practices scientifically proven to be harmful*'.[340] Further more, noting the philosophy of criminal law '*that the legislature should adopt progressive laws at times, educate and guide the public to dissociate itself from harmful traditional practices*', held that '*it is futile to issue a law that does not have the trust and support of the people for it usually remains impracticable'*.[341] Consequently, the code outlawed traditional practices that are believed to be harmful to the health and inflicts bodily injury or mental impairment.[342] More over, some TM practices related with magical and spiritual healing are stipulated as petty crimes punishable up on private complaint to the extent TMPs deceive users for gain.[343] Nonetheless, this does not mean that TM practices are totally banned by the law. Therefore, when we talk of protection

[338] Getachew Addis, et al., *Perceptions and Practices of Modern and Traditional Health Practitioners About Traditional Medicine in Shirka District, Arsi Zone, Ethiopia*, 16(1) ETHIOP. J. HEALTH DEV. 19, 19 (2002); Anders Jeppsson, et al., *Health Care Providers' Perceptions on Harmful Traditional Health Practices in Ethiopia*, 17(1) ETHIO. J. HEALTH DEV. 35, 35-44 (2003)

[339] The Criminal Code of the Federal Democratic Republic of Ethiopia 2004, Proclamation No. 414/2004 [here in after Criminal Code] Preface Parag. 3

[340] *Id.*

[341] *Id.*

[342] *Id.*, Arts. 561-570

[343] *Id.*, Arts. 700 & 861

of TMK through out this chapter, it is referring to practices that are not outlawed by the criminal code.

4.6.2. *Health and Drug policies and Related Laws and Institutions*

Several policies recognize TM as an important aspect of providing primary health care in Ethiopia. The national health and drug policies, for instance, place TM as one of the main priorities of the health policy and provides to give due emphasis for the development of the beneficial aspects of TM and its integration to the modern health care system after ensuring its safety and efficacy.[344] The general strategies adopted include identifying and encouraging the utilization of its beneficial components, coordinating and encouraging research including its linkage with modern medicine and developing appropriate regulation and registration of practitioners.[345]

The Drug Administration and Control Authority (DACA) is responsible government organ for preparing standards of safety, efficacy and quality of TM.[346] It is also empowered to register TMPs and give license for the use of TM in the official health services.[347] The national research institute established to conduct research on both traditional and modern drugs is the Modern and Traditional Drug research department of Ethiopian Health and Nutrition Research Institute (EHNRI).

Long after, the promulgation and establishment of the abovementioned policies and institutions, in 2009, the parliament passed Food, Medicine and Health Care Administration and Control Proclamation.[348] The proclamation bans use of TM without due evaluation and registration by relevant authority.[349] It further introduces a mandatory requirement for TMPs to obtain practice license, without having it no person is legally allowed to practice TM.[350]

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[344] Ministry of Health, Health Policy of the Transitional Government of Ethiopia, Addis Ababa, Ethiopia, (1993) Art.4; and, Ministry of Health, National Drug Policy of the Transitional Government of Ethiopia, Addis Ababa, Ethiopia, (1993) General Policy, parag. 3, Policy objective Parag. 6, Strategies parag. 9
[345] Health Policy, *Id.* strategies
[346] Drug Administration and Control Authority (DACA) was established in 1999 by Drug Administration and Control Proclamation, Proclamation No. 176/1999, Art. 6(8)
[347] *Id.*
[348] Food, Medicine and Health Care Administration and Control Proclamation, Proclamation No. 661/2009
[349] *Id.*, Art. 45
[350] *Id.*, Art. 46(1)

The practitioner license granted is of provisional kind that needs renewal every five years.[351] Additional requirement to have a certificate of competence issued by the competent authority is mandatory to manufacture, distribute or sell TM.[352] Like the TMPs license, the certificate of competence is only granted for period of one year.[353] Penalties are specifically prescribed for violation of these provisions of the law related with TM. That is, any person who violates these provisions shall be punishable with imprisonment of not less than one year and not exceeding three years and with a fine of not less than Birr 5,000 and not exceeding Birr 10,000.[354]

Although these policies and institutional arrangements do not directly concerned with protection of TMK, the important feature of these machineries shall not be disregarded viz. registration of TM practitioners, integration of TM in to the health care system and ensuring the safety and efficacy of TM. In spite of the promulgation of the necessary policies, laws and institutions nothing has been done in the actual practice to implement them while TM has been widely practiced in open markets.[355] Currently, DACA has made an initiative to establish a systematic way of registration and licensing to practice TM in accordance with the proclamation, by setting minimum standards of safety and efficacy of TM and its practitioners.[356] Until the time DACA transform the abovementioned policies and laws in to actual practice, there is neither registered and licensed TM practitioner nor TM the safety and efficacy of it is tested and evaluated.[357]

4.6.3. *Environmental and Biodiversity Policies*

In addition to the above discussed policies, the environmental and biodiversity policies are essentially important in recognizing TK explicitly.[358] Both policies give due emphasis to the communal nature of TK. Amusingly, the environmental policy provides for the creation by law of a system '*for the protection of community intellectual property rights'* which seems to

[351] *Id.*, Art. 46(2)
[352] *Id.*, Art. 47(2)
[353] *Id.*, Art. 47(3)
[354] *Id.*, Art. 59(1)(o)
[355] ዳዊት ዲቃሶ፣ የባህል ህክምና በኢትዮጵያ ከየት ወደት? 7(381) ሜዲካል ጋዜጣ፣ ነሐሴ 19, 2002፣ ገፅ12፣ [Dawit Dakiso is DACA inspection and law enforcement deputy directorate]
[356] *Id.*
[357] *Id.*
[358] Environmental Policy of Ethiopia, Addis Ababa, Ethiopia (1997); and, National Policy on Biodiversity Conservation and Research of Ethiopia, Addis Ababa, Ethiopia (1998)

underline the proprietary nature of TK.[359] However, there is no detailed strategy on how this can be achieved. The biodiversity policy on its hand, recognizing the role TK plays in the conservation of biodiversity, puts policy guidelines to the protection of TK and ensuring that communities share the benefits accrued from the utilization of genetic resources and TK.[360] To that end, it underlines the need to survey, assess, document, study, improve and utilize TK; and enact ABS law with the participation of the communities concerned.[361] Accordingly, the law on Access to Genetic Resources and Community Knowledge, and Community Rights was enacted in 2006. Following section is the discussion on ABS regime of Ethiopia.

4.7. *ABS Regime*

4.7.1. *Background*

Ethiopia is a party to the CBD, which requires member states to encourage equitable benefit sharing arising out of the utilization of TK. The convention also obliges member states to enact access legislation in order to facilitate access to genetic resources and to ensure equitable benefit sharing of the use of these resources.[362] As said in the previous section, ABS regime under the umbrella of the CBD is not limited to genetic resources but extends to TK associated with genetic resources. Ethiopia as a member, therefore, required to take legislative measures to fulfill its international obligation.

Ethiopia shows an interest on the implementation of ABS regime, by actively participating in international negotiations of the same matter. For instance, Ethiopia is one of the first members of the CBD to propose that the CBD '*examine the relationship between TRIPS and the CBD.*'[363] Specifically Ethiopia recommended the secretariat of the CBD:

> *[R]equest the WTO/TRIPS Council to take into account and accommodate the concerns of the Contracting Parties to the CBD before taking any decisions or*

[359] Environmental Policy, Sec. 4.7
[360] Biodiversity Policy, Sec. 2.1
[361] *Id.*, Sec. 3
[362] UN Convention on Biological Diversity, June 5, 1992, reprinted in 31 ILM 822 [here in after CBD] Art. 15(7)
[363] Dominic Keating, *Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 525, 528 (2005) *cited in* Jonathan Carr, *Agreements That Divide: TRIPS vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 J. TRANSNATIONAL LAW & POL'Y 131, 137 (2008)

measures in relation with the TRIPS Agreement that may affect the protection of TK.[364]

Furthermore, Ethiopia's interest in the protection of TK and ABS regime can be inferred from its pioneer role in the promulgation of 'African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Genetic Resources'.[365] Accordingly, Ethiopian parliament passed Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation [Ethiopian ABS law or the Proclamation].[366] As stated in the preamble of the law, its promulgation is guided by the CBD and the African model law.[367] That is, while implementing its international obligation, it is also using its right to regulate access as it has an interest in such kind of regime.

4.7.2. *Objective*

Unlike the African model law,[368] Ethiopian ABS law does not explicitly refer the protection of TK as the basic objective of the law as enshrined in Art. 3 which reads the objective:

> *[…] is to ensure that the country and its communities obtain fair and equitable share from the benefits arising out of the use of genetic resources so as to promote the conservation and sustainable utilization of the country's biodiversity resources.*

However, the preamble repeatedly states the necessity to recognize, protect and encourage TK.[369] Thus, it can be said that protection of TK and ensuring that its holders gain fair benefit arising out of its utilization is also one of the tenet objective of the proclamation, which can be inferred from the preamble and other substantive provisions discussed below.

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[364] *Id.*
[365] African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Genetic Resources adopted by OAU, 2000. [here in after Africa Model Law] It was originally drafted by the Ethiopian Institute for Sustainable Development (ISD)
[366] Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, Proclamation No. 482/2006 [here in after Ethiopian ABS Law]
[367] *Id.*, Preamble Parags. 3 & 4
[368] Africa Model Law, Part I [lists the general and specific objective of the law]
[369] Ethiopian ABS Law, Preamble Parags. 5-7

4.7.3. *Subject Matter of Protection*

With regard to the terminology used to refer to TK, it prefers to use '*community knowledge'*, which is also shared by African model law; and defined it as '*knowledge, practices, innovations or technologies created or developed over generations by local communities on the conservation and use of genetic resources'*.[370] This shows that it gives due emphasis to the communal nature of TK. As noted elsewhere in this chapter that TK especially in the field of medicine can be exclusively held by individuals, but the ABS law does not address this kind of TK and thus fails to give protection.

From the above definition, it is clear that TK covered by this proclamation is limited to those genetic resource associated TK. Its limitation to TK only associated to genetic resources has an implication to TMK. TM may involve non-medication therapies like spiritual therapies manual techniques and exercises that can be carried out without using any medication, which are not covered by the ABS law.[371] This means, such type of TMK are not covered by the proclamation. In addition, TM which is of medication therapy may use materials other than genetic resources, for instance minerals.[372] It is reported that more than 95 *percent* Ethiopian TM preparations are of plant origin.[373] If that was the case, the ABS law can cover substantial portion of TMK found in Ethiopia, but not all. Generally, the scope of TK covered by the proclamation is not wide enough to address all TK/TMK.

4.7.4. *Terms of Protection*

The ABS law grants ownership right to local communities over their TK. In the identification of local communities it defines them as '*a human population living in a distinct geographical area in Ethiopia as a custodian of a given genetic resource or creator of a given community knowledge'*.[374] It consequently affirms the inalienable rights of local communities to use and regulate access of their TK and share the benefit arising out of the utilization of their TK.[375]

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[370] *Id.*, Art. 2(14)
[371] WHO TM Strategy, *supra* note 58, at 7
[372] *Id.*
[373] Government of the Federal Democratic Republic of Ethiopia, *National Biodiversity Strategy and Action Plan*, Institute of Biodiversity Conservation and Research, Addis Ababa, Ethiopia 27 (2005)
[374] Ethiopian ABS Law, Art. 2(9)
[375] *Id.*, Art. 6

4.7.4.1. *The Right to Use and Recognition of Customary Law*

The first right granted to local communities is the right to use their TK and exchange the same with other local communities.[376] The only limitation put here is that it shall be in accordance with customary norms and practice of TK holder local communities.[377]

Under Article 10(1), it further mentions the protection of community right over their TK as they are enshrined in the customary practices and norms of the concerned communities. For such kind of protection under customary law neither non registration nor publication/oral disclosure of TK will bar the entitlement.[378] The provision, however, does not clearly state what customary community right is. As the country is a multi ethnic nation with diverse cultural norm, it would be vein to determine what customary law is and how it would protect TK in simple and general terms. Therefore, it sounds good to leave it to be determined case by case depending on the customary law available in a given community. What the ABS law guaranteed here is that knowledge will not disseminate or used by others contrary to the customs and beliefs of the community. For instance, if certain knowledge is restricted to the given community in which its dissemination to or use by others is contrary to customs and beliefs of that community, its dissemination/use by others contrary to customary law is declared unlawful. What will be the remedy if some one violates this rule? The penalties listed in the proclamation do not address this issue. The more probable answer to the question is that the remedy also will be with in the ambit of customary norm.

One thing that should be raised here is whether this recognition of customary law extends to cultural norms which give IP type of right to individuals or members of a family (clans) who hold TMK. For instance, Brehony's narrative of TM system in Oromia Regional State Borana area is the best example of such kind of cultural norm that bestow knowledge to specific family member.[379] That is, there is specialized TMK on medicinal plants believed to be

[376] *Id.*, Art. 8
[377] *Id.*
[378] *Id.*, Art. 10 (2) & (3)
[379] Brehony E.G., A study to determine a methodology for linking indigenous community practices in East Africa will outside development intervention strategies (1988) (Unpublished Ph.D. Dissertation National University of Freeland, Department of Agricultural extension, Agribusiness and Rural Development, faculty of Agricultural, University College of Dublin) *cited in* Endashaw, *supra* note 296, at 22

descended from two families in which the knowledge is passed from generation to generation with strict and formal cultural requirements.[380] And it is generally believed that if knowledge is not passed on formally, the medicine does not work and losses its power.[381] Therefore, no one can practice the knowledge without acquiring the knowledge in accordance with the custom of the society. This scenario shows how customary law can give IP type exclusive right to individuals or member of a family to practice TMK.

The provisions of the law are not clear whether recognition of customary law can be applied to those individuals or group of persons who hold TK and gain protection through the customary beliefs or customs. The African model law recognizes community rights to be protected in accordance with the customary law of the community in a very similar terms described by the Ethiopian ABS law.[382] However, it adds some thing novel that is not incorporated in the Ethiopian ABS law- community intellectual right.[383] The word property from intellectual property right is left out in the African model law. This trend is shared by other national legislations, for instance the biodiversity law of Costa Rica which recognizes the *sui generis* community intellectual right.[384] There is no clear and comprehensive legal frame work of what community intellectual right is. It is believed that the word 'property' is left out because of the common belief that such knowledge is held on behalf of the community and should not be subject to exclusive appropriation as provided in conventional IPR systems.[385] The intellectual right recognized in the African model law is not limited to knowledge held by the local community in general. Rather it also includes intellectual rights of traditional professional groups and in particular traditional practitioners, which seems to include even individuals.[386] As to the protection given it states that '*[it] shall be protected by the mechanisms provided under the [African model law]'.*[387] As the model law recognizes protection of TK in accordance with the customary law of the local communities, it can be

[380] *Id.*
[381] *Id.*
[382] Africa Model Law, Part III Parag. 17
[383] *Id.*, Part III Parag. 23
[384] Art. 82 of the Biodiversity law of the Republic of Costa Rica, Decree No. 7788, adopted by the Legislative Assembly of the Republic of Costa Rica in April 23rd of 1998 [*See*: section 3.4.1 Part II]
[385] Imiru (Concept Paper), *supra* note 315, at 4
[386] Africa Model Law, Part III Parag. 23(1)
[387] *Id.*

said that any right including IP type of right of individual or group of persons recognized under the customs of the society shall have the same legal protection.

To get back to the discussion of the matter on Ethiopian ABS law, no reference is made to protection of individuals. A number of provisions require the use and exchange of TK to be made in accordance with traditional systems. But these provisions are not meant to give a right to individuals as they are put in most cases as an exception to the general rule. Rather the law seems to show that it is not restricting the customary use of TK so that it will ensure and encourage the practice. The *travaux preparatories* of the law better assure the non applicability of the law to knowledge held by individuals. Whether the law is intended to cover individually held TKs was questioned during the discussion on the draft law, prepared by three permanent committees of the house of people's representative with concerned stakeholders. In the discussion, one of the presenters Ato Mesfin Bayo opined that:

> *Community knowledge is said if it is known by each member of the community, but not something that is known by only individuals. Individuals who hold traditional knowledge has the right not to disclose their knowledge but it is not covered by the draft proclamation. In fact, some times it may be difficult to separate individually held knowledge from the communal one.*[388]

This shows that the existence of TK held by individuals or only some member of the community is known by the drafters of the law. Thus, they excluded from the law cautiously, although it is not clear the rational behind it. In general, the law is not assumed to give protection to knowledge held by individuals even though the right might be recognized and well established by customary norms.

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[388] **የህዝብ ተወካዮች ምክር ቤት የገጠር ልማት ጉዳዮች ቋሚ ኮሚቴ፣ የህግና አስተዳደር ጉዳዮች** kሚ **ኮሚቴ እና የማስታወቂያና ባህል ጉዳዮች ቋሚ ኮሚቴ የጀነቲክ ሀብትና በማህበረሰብ ዕውቀት አርክቦት እና የማህበረሰብ መብቶች በተመለከተ በወጣዉ ረቂቅ ህግ ላይ ከሚመለከታቸዉ ባለሙያዎች ጋር ያካሄዱት ዉይይት ቃለ ጉባኤ፣ ገፅ** 4 (**ያልታተመ** 1998) [original Amharic my own translation]

4.7.4.2. *Access to TK and Benefit Sharing*

Access to TK can only be made with a written permit to be issued by the Institute of Biodiversity Conservation and Research[389] [IBCR] based on the prior informed consent (PIC).[390] However, the law puts three exceptions to this rule. Firstly, it lays down the customary use and exchange of TK by and among the Ethiopian communities, which is excluded from the ABS Law.[391] Secondly, organs of the state which are empowered by law to conserve genetic resources may not be required to obtain access permit to collect TK in the discharge of their duties; provided that they may not transfer it to third persons.[392] The last exception is that national public research, higher learning and intergovernmental institutions based in the country may get a special access permit for facilitated access without the need to strictly follow the standard access procedure, provided that the purpose is only for development and academic research and that such activities are undertaken within the country.[393]

Except in the above three cases any one- including Ethiopian nationals- who wants to access TK is required to make a written application to the IBCR.[394] IBCR has no right to permit access without the PIC of the concerned local communities. PIC is defined as the consent given to a person who wants to access TK by the concerned local community based on access application containing complete and accurate access information.[395] The information that should be provided by the applicant in order to satisfy PIC requirement is determined by the Council of Minister Regulation on Access to Genetic Resources and Community Knowledge and Community Rights [ABS regulation or regulation].[396] The ABS regulation sets different forms of access application for commercial and non commercial purpose. When access is intended for non commercial purpose, information the institution needs to provide in access application are, general information about the institution and some other technical

[389] IBCR is autonomous body of the Federal Government having its own juridical personality established by, Institute of Biodiversity Conservation and Research Establishment Proclamation, Proclamation No. 120/1998 [here in after IBCR Establishment Proclamation]
[390] Ethiopian ABS Law, Art. 11(1)
[391] *Id.*, Art. 4.2(a)
[392] *Id.*, Art. 11(4)
[393] *Id.*, Art.15(1)
[394] *Id.*, Art. 14(1)
[395] *Id.*, Art. 2(11)
[396] Access to Genetic Resources and Community Knowledge and Community Rights Council of Minister Regulation, Regulation No. 169/2009 [here in after ABS Regulation]

information.[397] When access is for commercial purpose the application shall include, general information about the access applicant; detailed access information including financial details, technical particulars that may include details of the genetic resource and associated TK to be accessed, details of planned collection mission, details of proposed use and benefit sharing information.[398]

There is no guidance in the proclamation on how local communities will give their PIC, as it only leaves to be determined by subsequent regulation. The difficult task here is identification of the local community which owns a specific TK. One of the powers and duties of IBCR as enumerated under its establishment proclamation is to conduct a study TKs available in the country on utilization, conservation and improvement of biological resources.[399] Considering this the regulation empowers IBCR to identify custodian of TK based on the survey it has undertaken and in consultation with relevant regional bodies.[400]

Different works have been made to study TMKs hold by different local communities. According to Ato Kebu Beletie- an ethno-biologist in IBCR, however, most of them especially made by ethno-botanical researchers are fragmented studies.[401] The project funded by the World Bank on the conservation of medicinal plants is a land mark initiative in which relatively comprehensive study that identifies TMKs known by local communities and documented the same.[402] Identification of TMKs and their custodians is the primary task to implement ABS law and better protect TK. Despite the great variety of studies made to identify TK and their holders, they are not sufficient enough and do not address all TKs given the diverse and rich TK systems the country has.[403]

Though it is found to be difficult, once local communities who hold the respective TK are identified, the next issue is how the local communities give their PIC. Where the concerned

[397] *Id.,* Annex II
[398] *Id.,* Annex I
[399] IBCR Establishment Proclamation, Art. 6(14)
[400] ABS Regulation, Art. 21(2)
[401] Interview with Ato kebu Beletie, *supra* note 308
[402] Interview with Ato Belachew Wassihun, In IBCR Information Desk Director (Former Medicinal Plant Genetic Resources Department Head), Addis Ababa (October 08, 2010) [Ato Belachew Was the focal person in the Medicinal Plants Conservation Project]
[403] Interview with Ato Kebu Beletie, *supra* note 308

community resides only in one Woreda, the consent will be given by the Woreda council.[404] The regulation rightly speculates the possibility that a single TK may be held by more than one community found in different geographical locations, and stipulates different mechanism on how community PIC is going to be obtained in such cases. Where the concerned communities reside in different Woredas or Zones of one region, provisional committee is established by the state council consisting members represented from such Woredas or Zones.[405] Where the concerned communities reside in area which falls in different regions, provisional committee is established by the house of peoples representatives consisting of members represented from such area where the community resides.[406] In all cases decisions are to be made in accordance with the procedures of their respected councils so that they may give or refuse PIC.[407]

There is no provision to oblige any of the councils or provisional committees to consult their respective communities they represent. Unless there is such kind of arrangement to participate local communities in decision making, PIC given by government organs is questionable and hardly possible to say it is consent of the community. Of course, it may be difficult to participate and gain unanimous approval of all members of the community. However, this shall be considered cautiously as it may create difficulty when applicants actually involve in collecting the knowledge. This is because of the fact that access is exercised with in and from the local communities. Hence, if communities are not consulted and fully aware of the situation they may resist any access.

The other thing that needs consideration is the level of awareness of both local communities and the government organs that are going to give PIC as to the law and the impact and implication of their decision and other related issues. According to Ato Kebu, lack of awareness will be a great difficulty in implementing the law and its regulation.[408] It is partly due to the fact that concerned government officials do not know even the existence of the law, and so much has to be done to create and develop awareness at least the concerned

[404] ABS Regulation, Art. 22(1)
[405] *Id.*, Art 22(2)
[406] *Id.*, Art 22(3)
[407] *Id.*, Art 24(1)
[408] Interview with Ato Kebu Beletie, *supra* note 308

stakeholders.[409] In IBCR, the responsible department for the implementation of the ABS regime- Genetic Resource Transfer and Regulation Directorate- is new department established in the late 2009 by the new Business Processing Reengineering (BPR), and it has planned to begin, create and develop awareness programme in this fiscal year.[410] The great challenge, however, is that while IBCR's main office found in Addis Ababa lacks material and human resources; it has no other branches in any other part of the country, which may create a difficulty in implementing its powers and duties effectively.[411] The ABS regulation, probably to minimize this problem, obliges regional states to enact detailed regulations and designate and strengthen institutions at all levels to implement the regulation and its proclamation.[412]

Any ways, the council or the provisional committees established in exercising their right to give PIC, has the right to refuse consent. But this right is qualified by requirement i.e. '*when they believe that the intended access will be detrimental to the integrity of their cultural or natural heritages'*. Is this the sole criterion to refuse their PIC? What if they believe that the proposed mechanism and arrangement for benefit sharing is not satisfactory/fair? It may not be reasonable to impose limitation of this kind on their right to refuse PIC if fairness is said to be made. What is fair to one may not necessary be the same for others. Here, the issue of awareness shall be raised for one more time. Upon identification of the local community, IBCR submit the access application together with decision proposal to the relevant organs.[413] If the organs have little or no awareness, they will more likely to adopt the proposal as it is. So, again communal PIC will be put under quotation as it may loss it's credibility of being consent of the community.

Once the concerned communities give their PIC via government representatives, the second important condition to access TK pursuant to the ABS law is benefit sharing. the ABS law states as one of the rights of local communities and pre-condition of access that local communities shall obtain fair and equitable benefit arising out of the utilization of their TK.[414] The kind and the amount of benefit to be shared by local communities from access to their TK

[409] *Id.*
[410] *Id.*
[411] *Id.*
[412] ABS Regulation, Art. 36
[413] *Id.*, Art. 23
[414] *Id.*, Arts. 9(1) & 12 (3)

is left to be determined case by case in each specific access agreements to be signed. Article 19 provides a non exhaustive list of monetary and non monetary benefits which may possibly accrued to the local communities.[415]

The ABS law empowers IBCR to negotiate and conclude access agreement based on the PIC of the local communities.[416] As noted above, the only condition for denial of consent by the local communities is if it is detrimental to the integrity of their cultural or natural heritage. These two statements indicate that let alone the local communities that do not directly participate in the PIC decision, even their representatives giving PIC do not actually have the right to participate and negotiate benefits accruing to local communities. Rather, it is the IBCR that negotiates and determines the benefits to be shared by local communities. This arrangement is basically flawed as it totally ignore the actual beneficiaries to participate in setting the terms of the agreement or the amount of the benefit and at least to challenge agreements they believe that are unfair or inequitable. One may argue to the contrary alleging that IBCR is the right institution to conclude environmentally sound and fair agreements; because, first, it has expertise to determine environment friendly collection systems; second, since most probably access applicants will be financially strong with more bargaining power and capable of mislead or cheat, the party to negotiate and deliberate shall be well equipped and informed of the situation to bargain and reach equitable and fair agreement, which can be done only by government institutions like IBCR. The argument, *prima facie*, appears to be sound, but this will not impede participation of the local communities or their representatives.

How the benefit is going to be shared by the local communities? The ABS proclamation states that the money obtained from access to TK shall put to the common advantage of the concerned local communities.[417] As the proclamation leaves the way it is to be executed to be determined by the regulation, the later proclaims the money to be used for financing development projects designed to benefit custodian of accessed TK.[418] Until the time the money is used to the intended project, it will be deposited in a special account called '*access*

[415] The benefits listed are license fee, upfront payment, milestone payment, royalty, research funding, joint ownership of IPRs, employment opportunity, participation of Ethiopians in the research, access to products and technologies developed through use of the TK, training at both institutional and local community levels, provision of equipment, infrastructure and technology support.
[416] Ethiopian ABS law, Art. 14(3)
[417] *Id.*, Art. 9(3)
[418] ABS Regulation, Art. 28

fund'.[419] All the money obtained from every access agreement will not be put in one account, rather a separate account with in the access fund for each access agreement has to be created.[420]

The power to prepare the project proposal designed to benefit the community is given to IBCR.[421] The power to determine how the money is to be utilized and allocated for the designed project is left to the Woreda council or provisional committees established by state council or house of people representatives, in the same procedure and composition of representative members that has been done in case of PIC.[422] When the beneficial community resides in an area which lies in different Woredas, Zones or regions, all of them are not entitled to equal share of the benefit. Rather, the share is distributed based on their relative contribution to the conservation of respective TK and/or related genetic resources that is considered by IBCR in preparing the project designed to benefit the communities.[423] The writer fails to see why the IBCR is empowered to determine priorities of the local communities. This is a clear indication of government's defective approach of saying '*I know what you need, much better than you'*. Any effort to justify this may not goes beyond a fig leaf attempt.

Generally, the deficiency of the ABS regime in Ethiopia as enshrined in both the proclamation and its regulation is its ignorance of the local communities who hold TK to participate in the decision making of access to their knowledge and benefit sharing agreement. Fikremarkos and Imiru rightly observed this shortcoming as they opined:

> *[…] [E]nsuring benefit sharing to local communities with their informed and full participation is the main objective of the ABS Law, but whether this objective has been translated into its provisions is questionable. Although the law places a great deal of importance to communities and capitalizes on their participation and decision making, that has remained largely at the level of*

[419] *Id.*, Art. 27(1)
[420] *Id.*, Art. 27(2)
[421] ABS Regulation, Art. 31
[422] *Id.*, Arts. 30 & 32
[423] *Id.*, Art. 29(2)

rhetoric and in fact the law accords all the decision making power to the government.[424]

4.7.5. *Implementation and Issue of Extra Territorial Application*

Any one who wants to access TK, save the exceptions, needs to posses access permit issued by the IBCR after conclusion of access agreement with the same. The ABS law specify non exhaustive list that shall be included in the content of the access agreement.[425] It further enumerates some of the obligations assumed by access permit holder during and after access, regardless of whether they are included in the access agreement or not.[426] Thus, access permit holders are obliged to observe the obligations they agreed on the contract and imposed on them by force of law.

Endorsement of law without effective implementation mechanism is just like toothless lion. In this regard, the ABS law mandated IBCR to follow up and ensure that access is carried out in accordance with the ABS law and the access agreement thereon, and to cause legal action in case of violation.[427] The first mechanism is to regularly follow up the progress of access at different stages and time. For that matter, the law obliges the access permit holder to give periodic report on the progress and status of collection and the research to IBCR.[428] IBCR on its hand obliged to follow up execution of the access agreement by receiving the reports made by the access permit holder or any other person, through inspection and any other manner it deems necessary.[429] In due course, IBCR, may limit, alter, suspend or terminate the terms of the agreement if it founds that access holder violates the provisions of the law and the agreement.[430]

The forgoing mechanisms might be effectively observed at the domestic level. The ABS proclamation and its regulation are national laws of Ethiopia, their application is in principle limited with in the territorial jurisdiction of Ethiopia. Thus it is noteworthy to establish a

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[424] Fikremarkos Merso & Imeru Tamrat, *Ethiopia's Experience in Access to Genetic Resources and Benefit Sharing: The Hope for Economic Benefits and the Risks for Research and Innovation,* at 12 Available at http://yaleisp.org/wp-content/uploads/2009/10/Merso-Tamrat-GRs.doc [accessed on June 12, 2010]
[425] Ethiopian ABS law, Art. 16
[426] *Id.*, Art. 17
[427] *Id.*, Arts. 27(1) & (7)
[428] *Id.*
[429] *Id.*, Art. 20
[430] *Id.*, Art. 21

mechanism to ensure that the law and access agreement is effectively enforced abroad. Two pertinent modes can be developed- i.e. the one aimed at preventing export of TK out of the country and if that could not be possible to develop legal machinery to enforce the agreement and the law in foreign countries. How the ABS law entertained this issue is discussed in the following paragraphs.

Once TK has left Ethiopia, it may be difficult to follow up whether the access agreement is observed or not. Even if possible, the provisions of the law and terms of the agreement may be breached. Once breached, enforcement of the law and the agreement in foreign countries is not an easy task as it involves complicated issues like enforcement of foreign judgment and other issues of private international law. In addition, it may not be affordable to poor country to go through costly court proceedings of enforcing the law and access agreement, for instance challenging patents. Therefore, the priority should be to prevent export of TK.

According to Article 12(6) of the ABS law, one of the preconditions for access to genetic resources in Ethiopia is that unless impossible, the company accessing the plant genetic resources must carry out the research in Ethiopia; this means that exporting genetic resources from Ethiopia is not allowed. What about research on accessed TK? Is that the free will of the access permit holder to conduct a research any where it deems appropriate? No single provision prohibits export of accessed TK. It may be due to the practical difficulty to regulate export of information, which is intangible. Since TK covered by the law is knowledge on use of genetic resources, one may argue that access to TK will include the genetic resources thereof. Although, there is a great deal of truth in this assertion, as genetic resources are not always limited in single geographical area the knowledge can be accessed without the need to have genetic resources so that left the country and conduct a research over genetic resources available there.

This shows that the law gives due emphasis to genetic resources not TK. It wouldn't be bad to require research to be conduct in Ethiopia. It is not only for the sake of preventing the non observance of the agreement and complicated enforcement issues. It will also give the country a share in technological knowledge and plays a paramount role in capacity building if the research is conducted in Ethiopia. Even though it is not included in the provisions of the law it is advisable to consider in the agreement.

The approach taken by the law is subjecting foreign applicants to additional requirement as a precondition to access TK; that is to provide '*a letter from the competent authority of his national state or that of his domicile assuring that it shall uphold and enforce the access obligations*'.[431] Neither the proclamation nor the regulation clearly states who the competent national authority is and how it enforces the obligations assumed by the applicant. In fact, it may be difficult to determine because government structures are different in different regions and legal systems. There is no agreement concluded to access TK that may show how it is going to be administered. To date, access agreements the country concluded are only on two endemic genetic resources- *Teff* (*Eragrostis teff*)[432] and *Vernonia (vernonia galamensis)*[433] – but not include knowledge of the local communities. In these agreements representatives from the embassies of the countries of origin of the applicants appear and sign as a witness.[434] In addition, once access permit is given to foreigners, collection of TK by the same will be performed accompanied by the personnel of IBCR or other relevant institute designated by IBCR.[435]

Whether this is effective in avoiding implementation problems is questionable. The problem happened relating to ABS agreement on *Teff* can give a lesson to rethink these provisions and their implementation too. It is reported that the company accessed *Teff* fails to observe the terms of the access agreement in many respects.[436] For instance, it fails to pay annual fee in accordance with the agreement; contrary to the terms of the agreement acquire and claim

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[431] Ethiopian ABS Law (2006), Art. 12(4)

[432] the *Agreement on Access to, and Benefit Sharing from Teff*, concluded between the Institute of Biodiversity Conservation and Research (Provider), the Ethiopian Agricultural Research Organization and Health and Performance Food International BV., (the Company), signed on 5 April 2005. The agreement is available at http://www.abs-africa.info/uploads/media/Teff-ABS-Agreement-2004-12_01.doc [accessed on May 15, 2010] [Teff (*Eragrostis teff*) is cereal crop originated and widely grown in Ethiopia that used to prepare staple food of Ethiopia (injera)]

[433] The *Agreement on Access to, and Benefit Sharing from Vernonia, concluded between the Ethiopian government (the Institute of Biodiversity Conservation and Research and EARO) and a UK company Vernique BioTech Ltd (Vernique)* [Vernonia (vernonia galamensis) is a tall plant with shiny black seeds that originated in Ethiopia and regarded for long as weed by the local farmers.] *See generally*: Abeba Tadesse, *Material Transfer Agreements on Teff and Vernonia – Ethiopian Plant Genetic Resources*, 2(4) JOURNAL OF POLITICS & LAW 77, 79 (2009)

[434] Fikremarkos & Imeru, *supra* note 424, at 11

[435] Ethiopian ABS Law, Art. 12(5)

[436] **በኢትዮጵያ አእምሯዊ ንብረት ጽ/ቤት የኮፒራይትና የማህበረሰቦች ዕዉቀት ልማትና ጥበቃ ዳይሬክቶሬት፣ እሸታ ሳይጠየቅባቸዉና ፈቃድ ሳይሰጥባቸዉ ጥቅም ላይ የዋሉ የጄኔቲክ ሀብቶች ዳሰሳ ጥናት፣ ገፅ** 4-5 (**ያልታተመ** 2002 **ዓ.ም**)

plant variety right over different verities of *Teff* developed; and develop new varieties without any authorization, are some of the reported violation claims.[437]

Regardless of all its defects, the ABS proclamation and its regulation made pioneer arrangement to deter possible conflicts between different local communities who share similar knowledge within Ethiopia. However, specific knowledge may not necessarily confined within the territory of Ethiopia. As knowledge systems are dynamic entities that change through contact, exchange and communication, different forms of knowledge can learn from each other. Thus, it is highly probable to find TK known by local communities of Ethiopian and other neighboring countries, especially near the border line. The probability is as high as the same ethnic group with similar language and culture reside in Ethiopia and other one or more neighboring countries. For instance, Afar People inhabit in four countries of the horn of Africa viz. Ethiopia, Eritrea, Somalia and Djibouti. Therefore, the same TK especially TMK held by Ethiopian local communities can be found in other neighboring countries in which it might be difficult to trace the origin.

Set aside in neighboring countries, the medicinal value of the well known home remedy medicinal plant in Ethiopia, Tena Adam (*Glinus lotoides*), is reported to be known in Egypt and Mali.[438] How the ABS law try to address the issue? The answer is in bold disregard it! Is the ABS law only meant to cover TK only known by Ethiopian local communities? While it fails to address TK privately hold by an individual and/or known by some members of the local communities; if it waits to expect benefit from foreign bio prospectors, using TK known only by Ethiopians, it may end up with little or totally nothing. The provisions of the Nagoya protocol discussed in the forgoing chapter, which calls for collaboration in cases where TK is found in transboundary situation, are important to be considered by Ethiopia.[439]

The benefit sharing arrangement between the san people and South Africa's Council for Scientific and Industrial Research (CSIR) on the Hoodia plant can be cited as an example of best practice for this matter. Sans are Bushmen people of the Kalahari Desert scattered through four countries of the southern Africa – Namibia, Angola, South Africa and

[437] *Id.*
[438] JAY MCGOWN, *SUPRA* note 70, at 8
[439] Art. 8 of Nagoya Protocol [*See*: Section 3.3]

Botswana.[440] Although the san people have used Hoodia for thousands of years as a thirst quencher and an appetite suppressant, a patent was awarded to CISR in 1998 on these qualities without their consent and knowledge.[441] After campaigning for the rights of the San peoples, a deal was struck so that the San peoples could benefit from commercialization of the product developed over their knowledge.[442] The benefit distribution deal was also made between san peoples found in different countries to divide 75 *percent* of the benefit accrued equally between the san of Namibia, Angola, South Africa and Botswana; while the remaining 10 *percent* to be used as working capital to the Hoodia Benefit Sharing Trust; 10 *percent* to be kept as an emergency reserve; and, 5 *percent* to Survival International informs San (WIMSA) for administrative purposes.[443]

4.7.6. *IPRs and Disclosure Requirement*

One of the obligations of the access permit holder under the ABS Law is '*not [to] apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute.*[444]' As Fikremarkos and Imiru rightly noted the language used in the ABS Law in relation to IPRs is general and vague.[445] The phrase IP protection over TK accessed seems to imply that IPRs can be claimed over TK as it is, without any modification. Is the obligation cease to exist if substantial modification is made to the knowledge accessed? One may tend to answer in the affirmative after reading the subsequent provision which puts other IPR related obligation of the access permit holder to:

> *recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from.*[446]

In this disclosure of origin requirement, the commercial property protection- including IPRs- claim is made on the product developed using TK that may signal the need to modification. At

[440] Vermeylen, *supra* note 37, at 292
[441] *Id.*, at 17
[442] *Id.*
[443] *Id.*, at 172
[444] Ethiopian ABS law, Art. 17(13)
[445] Fikremarkos & Imiru, *supra* note 424, at 14
[446] Ethiopian ABS law, Art. 17(14)

first glance, the cumulative reading of the two provisions may lead to superfluous conclusion that the obligation to obtain consent of IBCR in IPRs application is only required when the claim involves no modification or innovation, and when it involves innovation based on the accessed TK the access permit holder obligation is only to recognize and disclose the origin of TK used and lead to the invention.

Perfectly, this will be simplistic conclusion. There need to be an objective interpretation. First, the purpose of the law is not to handover the monetary interests to be accrued from TK to corporations; rather fair and equitable benefit sharing is always at the heart of the proclamation and its regulation. Argument and conclusion of the forgoing kind will defeat the very purpose of the law. Second, joint ownership of IPRs is among the listed modes of benefit sharing.[447] This could be achieved either by including a provision on the agreement for that matter or in the absence of that by enforcing the obligation to obtain consent, thus, in due course, IBCR will make a deal to further benefit sharing agreement including joint ownership and any other benefits. Third, as noted earlier TK which is covered by the proclamation is the one which is known by every member of the community. This will all destroy the novelty requirement under the patent law of Ethiopia, as Ethiopian patent law irrespective of the manner of disclosure requires absolute novelty if an invention is said to be patented in Ethiopia.[448] In general, it is hard to assume that the law intends to allow access permit holders to claim IPRs over accessed TKs as they are; and once they make modification which accounts inventive step freed them from any obligation to request permit from IBCR unless clearly agreed. This is only the problem of poor legislative drafting, which fail to put the message of the law in unambiguous, clear and consistent statements and phrases. The general message of the word shall be read as: 'the access permit holder can not apply to any kind of IPRs to inventions derived using accessed TK with out obtaining explicit written consent from IBCR and conclude further benefit sharing agreement'; and the second is extra obligation that would be applied in addition to the first one.

As discussed in the previous chapter, one of the issues debated in many international fora relating to TK is the disclosure requirement in patent applications. Developing countries

[447] *Id.*, Art. 19(6)
[448] Art. 3(2) of Inventions, Minor Inventions and Industrial Designs Proclamation, Proclamation No. 123/1995

proposed that patent applicants to inventions, which includes and/or derived from TK to disclose the origin of TK and provide evidence of PIC and benefit sharing. The provision of the ABS law which is separately indented and discussed before only requires the access permit holder to '*recognize the locality where TK accessed as origin'*. The obligation does not extend to provide evidence of PIC and benefit sharing. This may be due to the fact that the obligations listed under the provision are only to those who are in possession of access permit. And with out PIC and benefit sharing they will never legally access any TK covered by the proclamation as the two are pre conditions to grant access permit. Some thing that is unique to the proclamation is that it requires not only to disclose the country as origin of TK, but also the locality form where TK is accessed.[449] What if the applicant fails to disclose the locality in its patent application? Will the patent be revoked if it is granted in Ethiopia? As long as PIC and benefit sharing requirements are met by the patent applicant, the writer is of the belief that the mere failure to recognize the place of origin will not cause to revoke granted IPRs.

4.8. *TMK and IPR Laws*

4.8.1. *Patents*

Currently in Ethiopia, patent is regulated by the Proclamation on 'Inventions, Minor Inventions and Industrial Designs'[450] and the Regulation[451] issued forthwith. The Proclamation provides for patent protection for invention that is new, involve an inventive step and be capable of industrial application.[452] The proclamation requires a single individual to be identified as an inventor.[453] As said elsewhere, TK is developed inter-generationally, where in most cases it is difficult to trace the initial time of the first invention and inventors. As it is difficult to identify a single individual as an inventor of TK, *a priori,* one can not claim patent right over TK. This does not mean, however, that joint invention is not recognized under the patent proclamation. To claim joint ownership of patent the law requires one or more persons to jointly involve in the invention and to the same goal.[454] But this is not

[449] Fikremarkos & Imiru, *supra* note 424, at 16
[450] Inventions, Minor Inventions and Industrial Designs Proclamation, Proclamation No. 123/1995 [here in after Patent Proclamation]
[451] Inventions, Minor Inventions and Industrial Designs Regulation, Regulation No. 12/1997
[452] Patent Proclamation, Art. 3(1)
[453] *Id,*. Arts. 2(3) & 8
[454] *Id,*. Art. 7(2)

the case for TK holders as they only make changes to and develops the previous knowledge to adapt to the new environmental and socio economic changes.

In addition, the wide usage of TK defeats the novelty requirement of the patent law. This is because of the fact that article 3(2) of the proclamation require absolute novelty of an invention in which every disclosure irrespective of its form and place accounts prior art. Further more, a plant and animal variety on which most TMK based is non-patentable.[455] In general, patent right as it exists now is not ideal form of protection to TK/TMK. [The practical and theoretical reasons discussed in chapter 3 *mutatis mutandis* can also be applied here]

Considering the direct impact of patents on patented products that will create hardship to the poor to access medicines essential for their survival, it is not even advisable to extend patent protection to TMK in Ethiopia.

4.8.2. *Trade Marks and Geographical Indications*

In Ethiopia trademark protection is acquired through registration according to Trade Mark Protection Proclamation.[456] For the purpose of TMK, trademarks may be used to indicate biodiversity friendly products or to show that TM products are generated from natural substances without any chemicals or genetically modified organisms to increase their attractiveness in the market.[457]

Law for the protection of geographical indication in Ethiopia is merely at draft level. Thus, till the time the draft bill is endorsed by the parliament there is no comprehensive law on geographical indications. According to Ato Abebe, protection of TMK is not among the purposes the draft law envisaged to achieve.[458] Rather, it mainly aimed at prevention of falsely labeled products by using name of well known origins of recognized genetic resources like coffee.[459] It is not clear why this can not be used to prevent labeling of TM products as

[455] *Id.,* Art. 4(1)(b)
[456] Trade Mark Protection Proclamation, Proclamation No. 501/2006
[457] Imiru (concept paper), *supra* note 315, at 36
[458] Interview with Ato Abebe Tesfa, In EIPO Trade Marks and Industrial Design protection and Development process Director, Addis Ababa (October 20, 2010)
[459] *Id.*

originated from some geographical area that assumes good reputation either from the knowledge of the communities/practitioners or the suitable environment for production of efficacious medicinal plants. If a certain TM from specific area has special quality, the principle of geographical indication can be applied to protect TMK so that it could maintain the economic value of locally produced TMs.

Trade marks and geographical indications may prevent commercialization of TMs by third parties using them so as to attract consumers. However, they are not meant to protect substantive TMK in a strict sense. As already described in the previous chapter of the same title, protection by distinctive signs is not an end in itself to generate value to the title holders and do not prevent commercialization of TMs by third parties under a different trademark or geographical indication, or without having thereof. [See: Chapter 3.2.2.3]

4.8.3. *Trade Secrets*

There is no comprehensive law especially designed to protect trade secrets in Ethiopia nor it is part of the conventional IP system. However, the criminal code and recently passed Trade Practice and Consumers' Protection Proclamation[460] [trade practice law/proclamation] have some provisions relevant to protection of trade secret. The Trade Practice Proclamation outlaw unfair competition and define unfair competition as '*any act or practice carried out in the course of trade, which is dishonest, misleading, or deceptive and harms or is likely to harm the business interest of a competitor*.'[461] The trade practice proclamation, further give an illustration of acts constitute unfair competition and hence prohibited. Among the listed prohibited acts, in particular two are directly concerning trade secret, reads as:

> *any act of disclosure, possession or use of information, without the consent of the rightful owner of that information, in a manner contrary to honest commercial practice.*[462]
>
> *[…]*
>
> *[and] obtaining or attempting to obtain confidential business information of another business person through his ex-employee or obtaining the information*

[460] Trade Practice and Consumers' Protection Proclamation, Proclamation No. 685/2010
[461] *Id.*, Art. 21(1)
[462] *Id.*, Art. 21(2)(b)

to pirate his customers or to use for purposes that minimize his competitiveness.[463]

From these provisions, the information has to be secret is self-evident inasmuch as what is prohibited is the acquisition, disclosure, or use of confidential information contrary to honest commercial practice. Though the legislation fails to pin down the nature of the sort of information that it purports to protect in the first paragraph, from the phrase '*in the course of trade'* stated in the definition and as only business information covered under the second paragraph, one can infer that the secret information protected in both cases is the one associated with undertakings related with trade/business not other social information.

Unlike the TRIPS agreement, discussed in the previous chapter, certain information to qualify for protection the proclamation neither explicitly require it to be commercially useful nor the owner is obliged to take reasonable steps to keep the information secret. What it requires is that the information be secret, which is only known by the rightful owner. But, it may be erroneous to up hold that commercial usefulness and effort of rightful owner of the information is irrelevant. Because, first, as harm is raison d'être of unfair competition, it is difficult to imagine harm for non valuable information; second, unless the person who hold secret information takes reasonable step to keep it secret, there will be no dishonesty in part of the person acquiring the information.

In case of violation of these prohibitions the proclamation provides for civil and criminal liabilities.[464] Concurrent provisions that impose criminal liability are also found in the criminal code.[465] Compared to the punishments stipulated under the trade practice proclamation the criminal code is not that much harsh, as the former in addition to

[463] *Id.,* Art. 21(2)(f)
[464] *Id.,* Art. 35 & 49(3)
[465] Art. 719 of the Criminal Code, reads as:
'*Whoever intentionally commits against another an abuse of economic competition by means of direct or any other process contrary to the rules of good faith in business, in particular: […] (d) by granting or offering undue benefits to the servants, agents or assistants of another, in order to induce them to fail in their duties or obligations in their work or to induce them to discover or reveal any secret of manufacture, organization or working; or (e) by revealing or taking advantage of such secrets obtained or revealed in any other manner contrary to good faith,*
is punishable, upon complaint, with a fine of not less than one thousand Birr, or simple imprisonment for not less than three months.'

administrative measures and civil liabilities imposed, a person who violates the rules is punishable with more sever criminal penalty.[466]

As described anywhere in this paper, many TMPs held their knowledge secret. The reason why they kept it secret may differ from practitioner to practitioner. For some the reason may be because of their belief that once the knowledge is disseminated it will loose its power, while some fear that they will loose income or/and social recognition as many people may began to practice. What ever the reason it may be the truth is that they kept their knowledge secret.

As long as the knowledge is held secret, the above mentioned unfair competition provisions have the potential to protect some TMK. However, protection of TMK through trade secret may not be suitable for countries like Ethiopia due to multiple reasons. First, while further development of TMK and its wide usage shall be the priority issue, rendering trade secret protection to TMK does not guarantee further development of the knowledge. Second, it is well recognized that significant number of Ethiopian population depends on TM to meet thier primary health needs, due to its affordability, accessibility and other cultural factors. Conversely, giving exclusive right to TMK substantially decrease affordability of TM. Thus, only for the benefit of the few, the only affordable and accessible treatment may become out of the reach of majority of the population. Third, as mentioned in the previous chapter, trade secret law does not afford full scale property rights like patents. That is, the secret information can be legally acquired by innocent third party, for instance through reverse engineering. Therefore, trade secrets may not necessarily secure benefits to the right holders. Especially, as TM in most cases involves crude natural substance, it is more likely to be detected by modern science so that legally reproduced.

In general, protecting TMK boldly as it exists now shall not be the priority to Ethiopia. Rather, what is highly important is to integrate TM to the health care system through research and development to the benefit of the vast majority of the population and the national economy as a whole. In due course, the principle of fairness dictates that benefit should be

[466] Art. 49 (3) of Trade Practice proclamation: *[A]ny business person who violates [unfair competition rules] shall be punished with fine of 10 percent of his annual income or where it is impossible to determine his annual income with fine from birr 300,000 to birr 600,000 and with rigorous imprisonment from 3 to 5 years.*

accrued to TMK holders who preserve, develop and provide the knowledge. Not only to be fair, fair and equitable benefit sharing is also a strategic incentive to TMK holders to share their knowledge they otherwise will keep secret.

4.9. *Documentation*

It has been widely recognized that the vast knowledge surrounding TM is not fully documented and is conveyed from one generation to the next through word of mouth.[467] In the process of oral transmission valuable information can be lost when ever a medicinal plant is lost or when a TMP dies without passing his/her knowledge to others[468]. The oral transmission of knowledge may also give rise to the possibility of incompleteness, omission, misrepresentation or distortion of the original knowledge as time goes. Moreover, in the age of modernization where the younger generation underestimates TMK, it is reported that the knowledge is being lost at an alarming rate.[469] Due to the foregoing mentioned and other problems, TMK of the country faces uncertain future. There fore, calls from different scholars have been increasing for documentation of this national treasury so that rescue it from extinction.

In Ethiopia, even though TMPs are the best source of TMK, it was found very difficult to obtain their knowledge as they considered it as professional secret, only passed to the next generation orally as usual.[470] However, recent study shows that significant majority of TMPs who consider their knowledge as private secret, are volunteer to disclose the same if it is recognized and get monetary benefit thereof.[471]

At this time, where ABS law fails to recognize and hence to protect TMK held by TM practitioners, it is the view of the author that it is unlikely to get accurate information from them. While a tradition of trade secrets has allowed them to protect their knowledge historically, the idea of disclosure with in a public forum over which they have no control may be seen to represent a level of risk of exploitation that is unacceptable to many. Thus, naturally, reluctance or refusal to divulge information is a possible outcome. To avoid this,

[467] Getachew, et al., *supra* note 338, at 20
[468] Gidey, *supra* note 299, at 342
[469] *Id.*, at 341
[470] *Id.*
[471] Tibebu (progress report), *supra* note 315, at 4

there shall be a strong chain of trust between TMPs and registrar if effective and accurate documentation needs to be developed. The Dergue effort to develop national TMK database demonstrate the risk inherent in unwise documentation strategy. During the 1980's, the ex-government of Ethiopia (Dergue) introduced a requirement for traditional healers to register themselves as a TMPs and those who were not registered would not be permitted to practice TM.[472] Subsequent to this, all registered healers were required to disclose their formulations to develop a national formulary of TM.[473] As a result, many of them submitted inaccurate information leading to a national formulary that is not taken seriously by anyone who is informed about TM and about the process by which this knowledge was gathered and centralized.[474] They defended their actions by arguing that no one had the right to take away an important means of their livelihood without any assurance of involving them both in the testing of their drugs and in the sharing of the possible benefits should these medicines be found useful enough for mass production and marketing.[475]

The scenario perfectly underscores how it might be a waste of time and resource to go to documentation with out having any mechanism to build trust. Besides, the time and resource incurred to document inaccurate information, it has also deleterious negative consequence on future research and development to be conducted based on the stated information. That is, if bio prospector wants to use the information as a lead to develop new drug and fails to gain anything after incurring a huge investment, it will erode the good will of the TM system of Ethiopia. Therefore, in the future no one will approach Ethiopia, while the country lacks technological and resource capacity to effectively carry out by it self. Even, if the country tries to do so, it will be another waste of resource.

Documentation constitutes a record of prior art and hence an easy reference to patent examiners to deter and reject grant of erroneous patents for inventions based on TMK. Especially, in countries where novelty of an invention is assed in relation to documented prior art, it is the only available mechanism to deter grant of bad patents in those countries. Even

[472] Makonnen Bishaw, *Promoting Traditional Medicine In Ethiopia: A Brief Historical Review Of Government Policy*, 33(2) SOCIAL SCIENCE & MEDICINE 193, 196 (1991)
[473] *Id.*, at 197
[474] *Id.*
[475] *Id.*

though, it is possible to deter unauthorized use of TMK at the domestic level, in the absence of international norm to the same effect, it may be difficult to secure benefit from the use of TK. Of course, through documentation it is possible to challenge IPRs granted over TMK. But this is only to the extent the TMK used in the claimed invention constitute prior art so that defeats novelty. If TMK is used as a source of developing new drug leads by companies, a company would simply need to make a substantial change in order to be able to claim novelty- the act which may be easy for big pharmaceutical companies.[476] Therefore, until the time international norm is developed, documentation shall be done consistently with protection of confidential information. Otherwise, documentation will constitute a veritable mine field of information and opportunity for bio-prospectors and hence rather than reducing the likelihood of unauthorized exploitation it runs the risk of making TMK more readily available for biopiracy.

The information documented has to be organized in to easily navigable computer database so as to make it accessible to patent examiners so that deter grant of bad patents. However, documentation/database may not be an easy task for Ethiopia due to its expensive cost of development.[477] In addition, there will be a significant challenge to secure all the national treasury of information, as much of it is held in remote villages, by individuals and families who guard their knowledge due to cultural beliefs as a secret possession to be passed on only through family or other traditional way.[478] Thus, it will not constitute a complete record of TKs.

4.10. Alternative Approach

In the previous discussion, it is well established that IPRs- in particular patents- are not appropriate to positively protect TMK in Ethiopia. In addition, it has been argued that protecting TMK boldly as it exists today by giving exclusive rights shall not be the priority to Ethiopia. Rather, what is highly important is further development and integration of TM to the national health care system through research and development to the benefit of the vast majority of the population and the national economy as a whole. In due course, the principle

[476] Gerard Bodker, *Traditional Medical Knowledge, Intellectual Property Rights and Benefit Sharing,* 11 CARDOZO J. INT'L & COMP. L. 785, 803 (2003)
[477] *Id.,* at 804
[478] Gidey, *supra* note 299, at 341

of fairness dictates that benefit should be accrued to TMK holders who preserve, develop and provide the knowledge. Not only to be fair, fair and equitable benefit sharing is also a strategic incentive to TMK holders to share their knowledge they otherwise will keep secret.

To that end, employing a bundle of mechanisms is the best option available. Protecting TMK through trade secret, benefit sharing, documentation and introduction of mandatory disclosure requirement can be employed at the same time. Through documentation the knowledge can be preserved from possible extinction. By transforming the documented knowledge in to trade secret, TMK holders build a trust that their knowledge will not be appropriated. Similarly, benefit sharing from access to documented trade secret and its utilization provides economic return to its holders. Above all, bio prospecting based on the knowledge builds technological capacity of the country by involving Ethiopians in the research and development.

In this regard, to see the experience of Ecuador is worth mentioning. In Ecuador, the project, entitled '*transforming TK in to trade secret'* aims to enable traditional peoples and communities to benefit from bioprospecting through trade secret protection of their knowledge, produce big benefit to TK holders and the country as a whole.[479] This has been done through documentation and registration of TMK, in closed access databases, and checks are made to see whether each entry is not already in the public domain and whether other communities have the same knowledge.[480] If an entry is not in the public domain, the providers of the information have a trade secret.[481] The trade secret then disclosed to companies with benefit sharing guaranteed by a standardized contract.[482]

If curiously handled, documentation in addition to its preservation role is also an important instrument to identify TMK holders in the course of implementing the ABS regime. That is, after a complete documentation is undertaken, it is easy to identify knowledge held by different individuals or communities. For that matter, a cross checks can be made to see whether each entry is not already in the public domain and whether other individuals or communities have the same knowledge. If specific knowledge is found to be shared by

[479] Dutfield, *supra* note 34, at 259
[480] *Id.*
[481] *Id.*
[482] *Id.*

different individuals or communities, an arrangement to create a cartel among those who share it can be developed so that possible to avoid the danger of a price war competition among them.

Before engaging in to any registration of TK, first effective legal machinery needs to be devised with participation of the knowledge holders. The potential ways are, to expand the applicability of the ABS regime to cover knowledge held by individuals; develop a code of conduct for those who collect and register TK not to disclose the information they obtain in the discharge of their duties; persuade TMK holders that their knowledge will not be disclosed without their consent and share the benefit thereon.

Information collected needs to be organized in a way that patent examiners can easily retrieve it in course of searching for prior art, so that can *a priori* prevent the grant of bad patents and relieved from challenging the patent in substantially costly and lengthy court procedures. In addition, there shall be also other defensive method of protection through introduction of mandatory disclosure requirement in the patent law i.e. the provision that requires patent applicants to disclose TK used in the invention, evidence of PIC and benefit sharing arrangement made in accordance with the ABS law.

5. Conclusions and Recommendations

Conclusions

In spite of, or perhaps because of, the growing recognition of the importance of TK, protection of TK has become one of the contesting issues of modern international politics in which discussions and negotiations are taking place in many national and international fora. The fundamental truth, however, is that there is no precise and clear understanding among the international community on the subject matter TK and what it encompasses. Nonetheless, it is widely recognized that this should not be a problem to develop a legal regime to protect TK.

A number of general and specific objectives are sought form protection of TK. The underlying reasons and objective for the protection of TK are to recognize its value; preservation of TK, prevention of appropriation by unauthorized parties of components of TK; encourage and promote its use and its importance in development; and other equity considerations.

The modalities of protection proposed are of different kind ranging from using existing IPRs to establish *sui generis* regime. Due to multiple reasons, the existing IPRs proved to be ineffective, if not impossible, to protect TK. And now the discussion predominantly is on documentation of TK, increase the burden of patent applicants to disclose TK used in the claimed inventions, ABS regime and development of *sui generis* system of protection.

Sui generis system of protection has, indeed, been made by doctrine, is considered with in WIPO and has been pursued by some countries. However, since it must be specific to TK in all its breadth and yet satisfy the needs of particular forms of knowledge, let alone to reach international consensus on what a model law should look like, there is no clear and comprehensive *sui generis* regime in the countries which have taken an initiative.

Decade after TK emerged as an issue in the international agenda; little concrete progress has been achieved only in the CBD frame work through the adoption of the Nagoya Protocol. As the Nagoya Protocol requires ratification only by fifty states to come in to force, it is more likely to come in to force in the near future since developing countries- account majority of membership in the CBD- have more interest in the international ABS regime. Whether it will

be effective to the extent that fulfills the needs of many developing countries is questionable, as the CBD still does not include US- the alleged great boucher of TK- as full member and considering resistance of other developed states to see such kind of regime. The prospect in the development of effective international instrument to the protection of TK/TMK is just like a chiaroscuro, somewhere between dawn and sundown that make it difficult to predict the direction of the negotiation especially in WIPO and WTO. But, the worthwhile task undertaken by WIPO in clarifying the concept TK and other relevant issues related with its protection should not be underestimated.

In most cases, developing countries act in an organized fashion, which indicates the existence of common interest in the protection of TK. From its face, the general aspect of protecting TK induced by developing countries is limiting access to and use of TK, in particular by attributing property like control to TK holders and eventually to the state so that they could be able to elevate TK to the level of scarce resource, the use of which by third parties is reserved to those willing to pay. It also seems that developing countries, raise TK in IP fora as a negotiation strategy in response to developed countries demand to strength IPRs protection, meaning they either can smooth the current level of protection given to some fields they do not wish to extend protection- especially in pharmaceutical products- or to halt further strengthen of existing IPRs. One thing that needs consideration, however, is that different interests are also involved and pursued by different countries- including between developing countries themselves- from the negotiation and international protection. Generally, the world community is struggling with extremely complex and difficult issues which will require vision, good will, candor and shared will to resolve.

Although Ethiopia which believes itself rich in TMK take a lead in international fora to made proposal for the protection of TK, domestically very little work has been performed to protect TK in general and TMK in particular. Though different national policies recognize the essential role TM and its associated knowledge plays to the health care system of the country and the need to integrate it with the national health care system and develop it through research and development, it all remains at the level of rhetoric. In addition, the preliminary task for protection of TMK such as identification of the actual content of TMK available and its holders is missing. There is no comprehensive documentation of TMK in the country that

would serve as a tool to preserve it which is reported to be in the verge of extinction and used as evidence of prior art so that defensively prevent illegal claim of patents.

Whilst it is true that there is TMK held by individuals or group of persons to the extent of keeping it secret, the only national legal regime available concerning TK- ABS proclamation and its regulation- underscore communal nature of TK and thus fail to recognize TMK held by individuals. Besides, while prior to the development of ABS regime to TK, the actual holders of the knowledge should have been sufficiently informed and consulted in order to develop regimes which reflect their aspirations, interests, needs and customary practices and laws; whether this has been done prior to the enactment of the law is questionable. The provisions of the law that give all the power to decide on PIC, benefit sharing and determination of utilization of the money accrued, to organs of the government, all support the conclusion that communities do not play in the promulgation of the law. Thus it is hardly possible to say the law is the reflection of the needs of local communities. Moreover the ABS regime pays more attention to the establishment, regulation and commercialization of TK rather than to the recuperation, consolidation and strengthening of TK, the latter being more important to the large number of the population depend on it to meet their health care needs.

Given the fact that Ethiopia's TMK is not well developed, documented and integrated to the national health care system, as the Ethiopian proverb goes to say *'an exchange good discredited by its owner is not acceptable by a creditor'*, it is difficult to imagine that as it stands now will attract foreign bio-prospectors. This can be inferred from the absence of single researcher applying even to access TMK from Ethiopia. Conversely, TMK found in countries like China and India travel long positive distance to gain much popularity through out the world including Ethiopia so that attracts bio-prospectors and at the same time bio-squatters.

In the era of competition, where the principle of '*the fittest will survive'* guide the international trade relation, property titles can not guarantee benefits from knowledge that becomes relatively obsolete or that falls in to oblivion at the international level. As property is a market institution, in the absence of markets, where offer and demand actually meet, it is

literally worthless. More precisely, where property is supposed to operate in a museum rather than a market, all it will produce are high individual costs and few social gains. In view of this, international protection of TK that will hinder access to and use of TK is much to the benefit of countries like China and India. Therefore, if Ethiopia's interest is to have a share from the international trade on products and services related with TMK, much work needs to be performed to promote TMK of the country.

In addition to this, one thing that needs to underscored is that the implication of protection of TMK to the national health policy in general and the population who basically depend on it to meet their basic health needs in particular should have to be take in to consideration. Given the direct impact of property titles on price of products, it would not be advisable to employ legal regime that would give exclusive right to the holders of TMK. Bearing in mind, TMKs originated abroad are actually and have also the potential to be used in Ethiopia, politically speaking, protection of TMK by adaptation of national IPR laws to feet TMK special characteristics, may not be even desirable, since the availability of any adapted IPR protection might prove not only to the benefit of domestic applicants, but also to the benefit of those whom Ethiopia might wish to exclude from protection, since international IPRs law excludes any reservation of protection to nationals only. Therefore, IPRs or IP like property titles that would give exclusive rights are not appropriate tools to protect TMK in Ethiopia to achieve the objectives and priorities of the country, at least in the short term till the time the country reach a level of development- economically and research and development capacity- that calls for strong IPRs.

Although TMK found in Ethiopia is valuable both to the country and its holders, it should not be over stated. Over ambitious expectation of benefit to be derived from crude knowledge, and accordingly develop more stringent laws which prohibitively restrict and/or discourage access in order to use it directly as a raw material for development by value adding transformation, will have a deleterious consequence to the knowledge itself and those poor people actually depend on it. What is more important to Ethiopia and its inhabitants is its development and value added transformation to the level that meets the health needs of the country. In due course, it would create alternative income to Ethiopian farmers by growing and cultivating medicinal plants. If it gains recognition in the international market, export of

TM and medicinal plants also will be potential candidate sources of foreign exchange. This can only be achieved by rational and coordinated policy of research and development towards identifying actually and potentially valuable TM and associated knowledge, taking in to consideration the scarce technology infrastructure and capacity of the country to engage in research and development self sufficiently. Therefore, it is high time to develop well rehearsed policy priorities, strategies and incentives on accessing TMK that could help in addressing the country's need to boost its national capacity in research and innovation of its rich TMK and greatly contribute to the national health care system and of course to the benefit of its inhabitants and the general economy as a whole.

Recommendations

The protection of TK/TMK would entail efforts and commitments on part of individual nations and the international community. And a number of important works remains to be done to protect TK/TMK both at the international level and with in Ethiopia. Based on the findings of the analysis in the body part, this paper specifically recommends the following fundamental actions, to be undertaken:

1. **Internationally**

- The first question arising in relation to TK is whether measures for the protection of TK are to be taken at the national or international level. Given the transboundary nature and international dimensions of TK, provisions on the international level seem appropriate. However any regulation on the international level needs to be broad enough to embrace the diversity of TK. This paper therefore suggests that the international regime should establish minimal standards. International minimal standards should be supported by measures on the national level; in particular, this paper suggests that the international regime obliges parties to take measures to effectively implement the minimal standards on the national level.

- International ABS regime with in the CBD framework in particular the Nagoya protocol seems an appropriate framework for the protection of TK. And, the Nagoya protocol shall become in to force as soon as possible. Further, international regulations

are needed in order to prevent the race to the bottom phenomenon, which occurs when countries that dispose over transboundary TK compete for users by means of unduly lax regulations. This paper suggests that the multilateral benefit- sharing mechanism envisaged by the Nagoya Protocol shall be introduced.

- In order to support the full implementation of the ABS regime, amendments shall be made on other international instruments in the field of IPRs. In particular, this paper recommend for insertion of an enabling provision in the TRIPS agreement to oblige member states to require patent applicants to provide for, the source and country of origin of TK used in the invention and evidence of PIC and fair and equitable benefit sharing under the relevant national legal regime.

2. **In Ethiopia**

- While there is a number of evidence showing that TMK can be held by specialized TMPs, limitation of the scope of legal regimes designed to protect TK only to collectively held TK may turn out to be ineffective to achieve their goals. Hence, it is better to disregard the simple generalization that TMK is held by communities and thus any right available to local communities shall also be available to TMK holding individuals. For that matter, there is a need to amend the ABS proclamation so as to give legal protection to individually held TK. In addition, this paper highly recommend the amendment of ABS law in such a way that would increase the participation of local communities and TMPs in decision making, in particular they have to be equipped with the power to refuse access of their TK based on economic reasons.

- Documentation of TK is essential to preserve the knowledge, defensively protect acquisition of erroneous IPRs and to facilitate the implementation of the ABS regime. Therefore, there is a pressing need to conduct comprehensive documentation of TMK and its holders through aggressive studies to identify the actual contents and economic value of TMK and who actually holds and entitled to use and access it. To this end, there shall be clearly articulated strategies and legal measures which give incentive to those who disclose their knowledge.

- In order to ensure that the information individuals provide are accurate, they need to be assured that it is not meant to take away an important means of their livelihood. That is, they have to gain assurance that they will be involved in the testing of their drugs and in sharing the possible benefits if it is found useful for mass production and marketing. In addition, documents shall be kept secret if they wish so. Again to assure that the information remain secret until some one accessed based on a benefit sharing arrangement, a code of conduct shall be developed to those individuals or government organs collecting and/or in whose management the information is available, not to disclose the information they obtain in the discharge of their duties.

- In the course of documentation checks has to be made whether each entry is not already in the public domain and whether other communities or individuals have the same knowledge. If specific knowledge is found to be shared by different individuals or communities, an arrangement to create a cartel among those who share it shall be developed in order to avoid the possible danger of a price war competition among them in accessing it.

- The information in the documents shall be developed in an organized fashion (Ethiopian TMK Data Base) that could be easily retrieved by patent examiners, and accessed by them through conclusion of an agreement with terms of non disclosure.

- Development of a database for all TMKs which constitute a complete record of TMKs, however, may not be an easy task to Ethiopia due to the expensive cost of development and given the breadth and diversity of TMKs available with in the country. Therefore, defensive protection of TK by documentation shall be supported by disclosure requirement. And, this paper calls for addition of a provision in the patent law which requires patent applicants to mandatorily disclose TK used in the invention, evidence of PIC and benefit sharing arrangement made in accordance with the ABS law.

- Since TM practices significantly depend on plants, destruction of the ecosystem will result in the demise of the knowledge system. Thus, conservation (both in situ and ex situ) and sustainable utilization and harvesting methods of medicinal plants in

particular and biodiversity and perhaps the ecosystem in general, shall be adopted as part of strategy to preserve TMK and ensure its continued practice.

- Any policy and legal regime for the protection and promotion of TMK can only be viable and sustainable if the expectations and needs of the TMP and the communities within such knowledge is used and developed is fully taken into account. Therefore, in development of any legal machinery for the protection of TK/TMK TMPs should have to be fully consulted. They have also to be aware of the implications of the various alternatives that could be applied for the protection of their knowledge. For that matter, awareness creation and raising activity should be made to create chain of trust between the government and these individuals and/communities so that they will lend their hands to cooperate in the effort to implement the legal machineries developed. In addition to this, other stakeholders such as government agencies, academic and research institutions; the private sector and NGOs should also be adequately involved consulted in the policy and legal development process.

- Pragmatic steps shall be taken to the promotion and development of TMK system and integrate it to the modern health care system. Training of TMPs and introduction of TM in the educational curricula are strongly felt to be important for the improvement of the service and its gradual integration with the modern health care system. Once TMPs develop their knowledge through training they could be able to produce quality medicines and thus gain recognition. It is at this time that protection of TMKs through trade marks and geographical indications give its full meaning.

- In addition to endorsement of effective monitoring and compliance mechanisms, in order to effectively implement the legal instruments designed to protect TK, the capacity building of enforcement organs has to be undertaken. In particular, IBCR and EIPO have to be well equipped with material and human resources. Moreover, this paper, urgently recommends IBCR and EIPO to work closely and in coordination.

- While negotiating in organized fashion is beneficial to developing countries in which Ethiopia is not an exception, so as to coordinate resources and have strong bargaining position; Ethiopia needs to be curious in selection of countries or in joining groups.

Two basic reasons can be cited to justify this assertion. First, as the term developing country is an amorphous concept which consists of countries with diverse level of development both economically and TMK available, for instance Ethiopia and China, it would be vein to assume that all developing countries need similar form and degree of protection. Similarly, some developing countries with the great interest in liberalization of international trade in agriculture might use the issue as a bargaining power to get concession on it; that would in turn have adverse effect to Ethiopia and other net food importer countries. However, all this is shall not be interpreted in the wrong way that Ethiopia and these countries do not have common interest to share. Of course they do have.

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7. Strasbourg Agreement Concerning the International Patent Classification (IPC) of 24 March, 1971, as amended on 28 September, 1979.
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❖ **Interviews**

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2. Interview with Ato Belachew Wassihun, In IBCR Information Desk Director (Former Medicinal Plant Genetic Resources Department Head), Addis Ababa (October 08, 2010)
3. Interview with Ato Kebu Beletie, an Ethno Biologist in Institute of Biodiversity Conservation and Research (IBCR) Genetic Resource Transfer and Regulation Directorate, Addis Ababa (September 25, 2010)
4. Interview with Ato Tedla Mamo, In Ethiopia Intellectual Property Office (EIPO) Copy Right and Community Knowledge Protection and Development Process Director, Addis Ababa (September 17, 2010)
5. Interview with Ato Wondwessen Belete, In Ethiopia Intellectual Property Office (EIPO) Patent Protection and Technology Transfer Development Process Director, Addis Ababa (October 15, 2010)
6. Interview with Bekele Daba, Traditional Medical Practitioner and owner of Bekele and His Family Traditional Medical Center, Lege Tafo (October 17, 2010)
7. Interview with Dr. Getachew Addis, In Ethiopian Health and Nutrition Research Institute (EHNRI) Modern and Traditional Drug Research Department Director, Addis Ababa (October 22, 2010)
8. Interview with Haji Muhammad Awol, Traditional Medical Practitioner and owner of Haji Muhammad Awol Traditional Medical Center, Addis Ababa (October 10, 2010)
9. Interview with M/Geta Afework Getahun, Traditional Medical Practitioner and owner of Kokeb Birhan Traditional Medical Center, Addis Ababa (October 14, 2010)
10. Telephone Interview With Dr. Tewoldebirhan G/Egziabher, General Manager of Ethiopian Environmental Protection Authority (EPA), Addis Ababa (November 1, 2010)

❖ **Other Amharic Documents**

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3. **የህዝብ ተወካዮች ምክር ቤት የገጠር ልማት ጉዳዮች ቋሚ ኮሚቴ፣ የህግና አስተዳደር ጉዳዮች ቋሚ ኮሚቴ እና የማስታወቂያና ባህል ጉዳዮች ቋሚ ኮሚቴ የጀነቲክ ሀብትና በማህበረሰብ ዕዉቀት አርክቦት እና የማህበረሰብ መብቶች በተመለከተ በወጣዉ ረቂቅ ህግ ላይ ከሚመለከታቸዉ ባለሙያዎች ጋር ያካሄዱት ዉይይት ቃለ ጉባኤ** (**ያልታተመ** 1998).
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ANNEX

Sample Interview Questions

Ten individuals either in their individual or official capacities were interviewed. Interview questions were mainly semi structured open ended. All questions and interviews were also in Amharic but later on translated in to English and used in the thesis. Generally, at its core, interviews were made in the way that could answer the following questions.

Interview with TMPs

- From whom have you acquired the knowledge? How do you held and preserve the knowledge? Are you willing to convey your knowledge?
- Do you have any collaboration with modern health practitioners? Are you willing to cooperate with modern health practitioners/researchers?
- Do you support cooperation of modern and traditional health practitioners, and integration of the two systems?
- What do you think are the problems of TMK? Is there any support from the government?
- What are the solutions you sought for the improvement and protection of TMK?

Interview with Experts and Government officials

- Who holds TMK?
- Do you support cooperation of modern and traditional health practitioners, and integration of the two systems? What needs to be done to do so?
- Do you have any collaboration with traditional healers? What problems are identified?
- Do you think that Ethiopia is beneficial from international protection of TMK? Why?
- Is there any effort to document TMK and its holders? What problems you identify?
- Do you believe that current IP laws of Ethiopia can protect TMK?
- What is meant by community intellectual right?
- Is the ABS regime of Ethiopia sufficient to protect TMK? What gaps needs to be filled? Have you come across with problems in implementing the ABS law?
- What measures do the institute/authority/office take or intend to take to protect TMK?
- What are the problems encountered to protect TMK? What are the solutions you sought for the improvement and protection of TMK?