NATIONAL LAW SCHOOL OF INDIA UNIVERSITY

LEGAL FRAME WORK PROTECTION OF TRADITIONAL MEDICINAL KNOWLEDGE: WITH SPECIAL REFERENCE TO KERALA

(Under the Guidance of Pro. (Dr.) T.Ramakrishna)

Dissertation submitted in partial fulfillment of the requirements for the Degree of Master of Laws

SUBMITTED BY

ANJANA MOHAN,
ID NO: 299,
LL. M FINAL YEAR,
2007-2009.

DEVOTED TO LORD KRISHNA .....

WHO GUIDES ME THROUGH MY TEACHERS

WHO PROTECTS ME THROUGH PARENTS

WHO GIVE HANDS IN THE FORM OF MY FRIENDS

CONTENTS

CERTIFICATE

This is to certify that this Dissertation **"Legal Framework of Traditional Medicinal Knowledge with Special Reference to Kerala"** submitted by Ms. Anjana Mohan (ID. No. 299) for the Degree of Master of Laws of the National Law School of India University is the product of her bona fide research carried out under my guidance and supervision. This Dissertation or any part thereof has not been submitted elsewhere for any other degree.

Date: 20-05-2009

(Prof Dr. T. Ramakrishna)

Place: NLSIU, Bangalore

DECLARATION

I, Anjana Mohan, do hereby declare that this dissertation, entitled **"Legal Framework of Traditional Medicinal Knowledge with Special Reference to Kerala"**, is the result of the research undertaken by me in the course of my LL.M. Programme at National Law School of India University, Bangalore, under the guidance of Prof. Dr.T.Ramakrishna.

This work is in the final semester and is my original work, except for such help taken from such authorities as have been referred to at the respective places for which necessary acknowledgements have been made.

I further declare that this work has not been submitted either in part or in whole, for any degree or diploma at any other University or institution.

Date: 20.5.09

Anjana Mohan

Place: Bangalore

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June 2009 Anjana Mohan

ABBREVIATIONS

AD	:	anno demonic.
B.C.	:	Before Christ.
CSIR	:	Council of scientific and Industrial research.
IPR	:	Intellectual property rights.
NBA	:	National Biological Authority.
R & D laboratories	:	Research and Development laboratories.
SCIP	:	Supervisory Committee on Intellectual Property
TBGRI	:	Tropical garden and research institute.
TCM	:	Traditional Chinese Medicine.
TK	:	Traditional Knowledge.
USPTO	:	U.S. Patent and Trademark Office.
WHO	:	World Health Organization.
WIPO	:	World Intellectual Property Organization.

RESEARCH BACKGROUND

India is a nation containing invariable amount of natural resources in the form of medicinal and non medicinal plants. Kerala, Assam, Karnataka are some of the states where wide varieties of flora and fauna exist. India's tradition, culture, and way of life has been inextricably connected with its mother nature. Many of India's Local communities still live in forest for thousands of years. For them, that is their teacher, mother and good companion in the time of distress, for all of their problems, usually have only one answer– The Mother Nature and its never ending resources.

Whatever knowledge they are having with them has been passed to them by their ancestors, who themselves owe them to the Mother Nature. To put it in other way, the knowledge that they are having is the knowledge that is flowing to them because of their traditions and is therefore better known as "Traditional Knowledge". Such knowledge is not the intellectual property of any individual rather it belongs more to the community which has preserved that knowledge for generations. They carry with them some such secrets of nature and medicine that even science has failed to explore.

Once this fact of their rich traditional medicinal knowledge was realized by the industries, they started to exploit the resources and use the knowledge of indigenous communities to manufacture high-value products without acknowledging these communities and without sharing the benefits of their knowledge with them. The exploitation of their knowledge base has reached its climax and attempts have been made even to get their

medicinal knowledge patented. To recall the past I think, we all witnessed the case of neem patenting and "arrogya pachha" patenting. These instances opened the eyes of both scientific and legal community of India to the crying need of protecting the traditional knowledge. There were several hue and cries from various parts of the country. Recently, government of Kerala has come up with a new policy on June 2008, "intellectual property right policy for Kerala." So in this scenario the question remains how far this policy will meet the challenges of future? How this policy can implement in practical level? Is traditional IPR regime is effective in protecting the traditional knowledge of the people?

AIMS AND OBJECTIVES OF THE RESEARCH:-

The primary aim the researcher proposes is to analyze the legal position regarding traditional medicinal knowledge by doing an analytical and comparative study with reference to Kerala. The researcher would also be analyzing the initiatives taken at the international level in this regard. The ultimate aim of my research is make suggestions and recommendations for the better implementation of legal protection afforded to the traditional medicinal knowledge.

HYPOTHESIS

The present legal frame work is not adequate enough to protect the traditional knowledge of the communities actually owning them.

RESEARCH METHODOLOGY

The Researcher through this paper proposes to understand and explain the nuances of Traditional Knowledge, are analyze the same with reference to the position in Kerala. The research work is proposed to be partly doctrinal and partly empirical. For the fortification of my above mentioned objectives, the researcher shall be relying upon both primary as well as secondary sources. Researcher shall also be explaining the concepts involved in the research like traditional knowledge, indigenous people; etc.

METHOD OF DATA COLLECTION

The researcher proposes to make use of both primary and secondary sources of data. The work of primary data collection shall be taken up by the researcher through the questionnaire method of data collection. Further to ensure the universality of my empirical study shall also be taken care of through the selection of locations for my empirical research.

RESEARCH QUESTIONS

- What is meant by traditional knowledge?
- What is meant by indigenous community?
- Traditional knowledge and IPR protection.
- Distinguish between traditional knowledge holders and knowledge of the community ?

- How traditional knowledge can utilize for the benefits of both indigenous people and commercial exploiters?
- Are the legal checks sufficient to protect the interest of the indigenous people against the commercial exploiters?

METHOD OF WRITING:

The researcher would be following an analytical and descriptive style of writing. Findings of various authors shall used for the purposes of analysis and description. The researcher shall make an attempt to explain the concept wherever necessary. Sincere endeavors shall be made to maintain the lucidity of the language.

MODE OF CITATION

Researcher has adopted a uniform method of citation as indicated below.

Author, name of the book, volume, edition/year, place of printing.

Author, "title of the article", journal in which it is published, volume, year, Page no.

Web resources cited by direct link with the date on which accessed.

Further for the purpose of convenience the researcher shall be dividing the writings preferably in the following chapters:

INTRODUCTION

CHAPTER- I

EVOLUTION AND MEANING OF THE TRADITIONAL KNOWLEDGE

- EVOLUTION OF THE CONCEPT:-
- DEFINITION AND THE SCOPE :-

- DIFFERENCE BETWEEN TRADITIONAL KNOWLEDGE HOLDER AND TRADITIONAL KNOWLDEGE COMMUNITY

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- Critical evaluation of intellectual property policy - 2008
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CHAPTER VI:

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- SUGESSTIONS
- CONCLUSION

INTRODUCTION

Human communities have always generated, refined and passed on knowledge from generation to generation[1]. Their identity, culture, and development interlinked with these traditional practices. Often we could see one community may differ from the "daily practices" of other community. Such traditional practices may have a connection with their day to day life also. Or in other words, these traditional practices acted as a governing code of that particular community. Soon, these practices transmitted from persons to person, family to family, generation to generation, and at times even one clan to other clan. Later these traditional practices formulated in the form of traditional knowledge of that particular community. Unfortunately, when we consider innovation, we refer to only formal system of innovation namely that done in universities, industrial R&D laboratories, etc. Often not recognised is the technology innovation that takes place in an informal system of innovation, be it by artisans, farmers, tribes or other grass root innovators[2].

Interestingly , many societies in the third world have nurtured and refined systems of knowledge of their own, relating to such diverse domains as geology, ecology, botany, agriculture, physiology and health. These informal innovators have, therefore, generated such a rich store of traditional knowledge.[3]

So, Traditional knowledge refers to the knowledge, innovations and practices of indigenous and local communities around the world. It's usually collectively owned- a collective

[1] Commission on intellectual property rights, integrating intellectual property rights and development policy; report of the commission on intellectual property rights; 73 (2002).
[2] http://stp.unipune.ernet.in/ipr/tradi.htm accessed on 3.1.2009
[3] *ibid.*

property of the society. Traditional knowledge includes various areas such as traditional arts, folklore, cultural values, local language, medicines, plants and animals' etc. One can easily identify that spiritual knowledge, unique Games, sports, music, dances ceremonies, ritual performances and practices of any particular community, which is different and unique from others, then it can be termed as some of the traditional knowledge possessed by that particular community.

But, there may be questions arise whether this traditional knowledge is worth enough to protect or does it any way help the present humanity?

To address these questions, one should trace out the evolution and development of traditional knowledge and how it differed from the indigenous knowledge. This gives a clear appreciation of what the term "traditional knowledge" connotes and its scope and value in the present era.

CHAPTER – I

MEANING AND EVOLUTION OF TRADITIONAL KNOWLEDGE

The knowledge of the primitive man was limited therefore he believed that the causes for all his suffering – it can be a disease or other natural calamities – is because of wrath of Gods, or the invasion of "evil spirits" in to the body. The concept of disease in which the ancient man believed was known as the "supernatural theory of disease."[4] Medicine in the prehistoric times (about 5000 BC) was intermingled with superstition, religion, magic, and witchcraft[5].

But when we come to the earlier period of civilizations, Traditional health care system was prevalent in all the civilizations in one or other form. Though the earlier man connect all his deeds with God, but we could not ignore the traditional health care system prevalent in those days were just spiritual in nature or unscientific. The history reveals that, even in the oldest civilizations like Egypt, Mesopotamian (Babylonian) etc had a well defined form of traditional health care system existed. So there is no wonder that 200 BC ago, in Egypt, they had some knowledge of inoculation against small pox, the value of mosquito nets, and association of plague with rats and ill effects of alcohol consumption and so on.[6] Similarly in Mesopotamian civilization they formulated a set of laws called the code of Hammurabi, which governed the conduct of physicians and provided for good-health practices[7].

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[4] Park K. Man and medicine: Towards health for all. In : Textbook of Preventive and Social Medicine. 18th ed. Banarasidas Bhanot Publishers: Jabalpur; 2005. p. 1-5 as cited in Kushwah SS, "Public health learning and practice from hygiene to community medicine, health management and beyond issues: Challenges and options", Indian journal of community medicine , vol. 32, 2007 , p 103-107.

[5] Kushwah SS, "Public health learning and practice from hygiene to community medicine, health management and beyond issues: Challenges and options", Indian journal of community medicine , vol. 32, 2007 , p 103-107.

[6] *Ibid.*

[7] *Ibid*

In the medieval period, people of local traditions realized the medicinal effects of certain herbs, roots ad tubers. In almost all countries they developed their own method of healing practices. Among those traditional healing practices ayurveda, unani, siddha has holding a distinct place even in the modern system of medicine.

Traditional knowledge is ensuring food security and guarding health of millions of people in the developing world. In developing countries, up to 80% of the population depends on traditional medicines to help meet their healthcare needs[8]. Since this research paper is focusing upon the traditional medicinal knowledge, researcher is trace out only the evolution of traditional medicinal practices in various jurisdiction

1.1 EVOLUTION OF TRADITIONAL MEDICINAL KNOWLEDGE IN SELECTED COUNTRIES

1.1.1 China: -

The roots of Traditional Chinese Medicine (TCM)[9] date back more than 2000 years.[10]And it claims to be the world's first organized body of medical knowledge.[11] It is to be noted that some of the scholars believes that origin of the TCM goes back to even 5000 years which is unrecorded and based on legends[12].Chinese were early pioneers of immunization. Hygiene, dietics, hydrotherapy, massage, and drugs were all used by Chinese physicians.. They practiced vaccination to prevent smallpox[13]. The clinical diagnosis and treatment

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[8] Supra n, 1

[9] Although Traditional Chinese Medicine and Traditional Oriental Medicine are two terms used interchangeably, TOM generally refers to the system of Chinese medicine practiced until the early 1900s

[10] http://www.amfoundation.org/tcm.htm accessed on 8.5.2009.

[11] Supra n. 5

[12] According to the legend the origins of traditional Chinese medicine is traced back to the to three legendary

[13] emperors/mythical rulers: Fu Xi, Shen Nong, and Huang Di but historians believes that they were tribal leaders. According to the ancient texts, Shen Nong tasted a hundred herbs including 70 toxic substances in a single day, inorder to get rid of people's pain form illness. As there were no written records, it is said that the discoveries of

in Traditional Chinese Medicine are mainly based on the yin-yang and five elements theories[14]. Apart from these theories it based up on the six evils and seven emotions, and treating Zan-fu organ as core of the human body. Traditional Chinese medicine treatment starts with the analysis of the entire system, then focuses on the correction of pathological changes through readjusting the functions of the zang-fu organs .These theories apply the phenomena and laws of nature to the study of the physiological activities and pathological changes of the human body and its interrelationships[15]. The TCM therapies include acupuncture, herbal medicine, and qigong exercises etc. In TCM treatment is not based only on the symptoms, but differentiation of syndromes. They codified their medicinal theories and practices in to a book namely the Hung-Di Nei-Jing (Yellow Emperor's Cannon of Internal Medicine) and which extensively summarizes and systematizes the previous experience of treatment and theories of medicine, such as the meridian theory, as well as many other issues, including, physiology, pathology, prevention, diagnosis, treatment, acupuncture and moxibustion, tuina, etc[16]. During the Yuan Dynasty, China was controlled by Genghis Khan's vast Mongolian empire. During the period of Mongolian empire Chinese medicine became increasingly specialized and the understanding of acupuncture was further detailed. In 1368 BCE, the Chinese regained control of their land under the Ming dynasty. Li Shizhen, (1518-1593 CE) was one of the greatest physician and pharmacologist of the Ming dynasty. His major contribution to medicine was his forty-year work, which is found in his epic book Ben Cao Gang-mu (The Compendium of Materia Medica). The text

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Shen Nong was passed down verbally from generation to generation. http://www.purifymind.com/HistoryMed.htm accessed on 8.5.2009

[14] http://www.tcmpage.com/index.html accessed on 25.4 09

[15] *Ibid*

[16] http://www.purifymind.com/HistoryMed.htm accessed on 8.5.09

contains 1,900,000 Chinese characters and details more than 1,800 drugs, including 1,100 illustrations and 11,000 prescriptions, as well as record of 1,094 herbs, detailing their type, form, flavor, nature and application in treatment. This book was one of the greatest contributions to the development of pharmacology both in China and throughout the world. Materia Medica has been translated into many different languages and remains as the premier reference work for herbal medicine.[17] The General Treatise on the Causes and Symptoms of Disease and The Medical Secrets of An Official by Wang Tao are some of the other famous books contributed by the TCM to the world.

So it is needless to say , there are number of healing methods are available in TCM for treating different diseases ranging from common cold to deadly diseases like cancer AIDS etc.. According to TCM roasted Tangerine has medicinal qualities for curing the common cold. Similarly they have prescription for treating cough also. And it is interesting to note that they have made a division in the cough i.e., unproductive dry cough and chronic cough. While a mixture made up of hen's egg, edible oil, white sugar etc. using for the former type, a dish made up of pork and chest nut is using for the later. Apart from these they identified the medicinal qualities of honey and ginger; rock candy and banana etc for curing persistent cough.

[17] Supra n, 16.

1.1.2 Thailand: -

Traditional Thai Massage has a recorded history of over 2,500 years and this Ancient Massage is derived from thousands of years of traditional healing methods before its own beginnings.[18] Thai medicine is fine a blend of traditional medicinal system of India and the medical tradition of china. The historical progenitor of Thai medicine is Jivaka Kumar Bhaccha (pronounced by Thais as "Shivago Komarpaj"). He is consisdered by almost all practitioners as the "Father Doctor" of Thai medicine[19]. He was a renowned Ayurvedic doctor in his time, and is considered by Thais to be the original teacher of the Thai massage system as well as the source of Thailand's complex herb and mineral pharmacopoeia[20].

Even today a large number of the population in Thailand relies on traditional medicinal practitioners, including traditional birth attendants, herbalists and local medicinal plants to satisfy primary healthcare needs. Traditional medicine is quite popular in rural areas and villages in North Thailand.

Most local doctors are skilled in different aspects of traditional medicines but they usually practice a particular specialty. Even in those days medical practitioners were themselves divided in to different categories on the basis of their specialized field of medicine. The specialties of traditional medicines are herbal healing, bone blowing and spiritual healing[21]. Mor Muang is the term used to describe the local doctor.[22] A herbalist usually covers the entire spectrum of

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[18] http://www.thefreelibrary.com/Thai+massage+the+ancient+healing+of+Thailand:+explore+traditional...-a0110265053 accessed on 9.5.2009.

[19] http://www.taomountain.net/traditional-thai-medicine/thai-ayurveda.html accessed on 9.5.2009

[20] *Ibid*

[21] http://ezinearticles.com/?The-Traditional-Medicine-of-North-Thailand&id=858478 accessed on 9.5.09

[22] ibid

diseases and he formulates medication from herbs and other natural ingredients where as a bone blower is the one who specializes in wounds and broken bones and his responsibility to repair fractures and wounds by applying splints or poultices and then blowing and chanting incantations to the affected area[23]. A spiritual healer performs ceremonies and chants incantations to call on to the affected person's spiritual essence and then connecting to the patient's spiritual guide to cure and heal him[24].An example of Thai traditional knowledge is using of plao-noi plant for treating ulcer.

Traditional Thai medicine historically split in to three branches such as

1.1.2.1 Thai massage: - Traditionally practiced in Buddhist temples by monks specializing in this "manual manipulation", the work in Thailand today is no longer limited to the temple setting. In Thai massage it is not just the hands that are used to free tension from the recipient's body but the therapists feet, forearms, knees, and elbows as well. Northern style Thai massage is not painful also.

1.1.2.2 Dietary regimens and herbal medicine:- giving nutritional counseling to the client and also herbal mixture both for internal and external.

1.1.2.3 Thai Spiritual healing :-primarily focusing upon the meditation based on Buddhist principles .

Apart from these medicinal practices, "herb compressing" is a major traditional medicinal practice in Thailand. wherein which a wide variety of

[23] Supra n, 21
[24] *Ibid*

traditional herbs [25] will be pressed with and wrapped all over the body f the patient's body part. this traditional treatment can improve tissue congestion, stiff joint, muscle strain condition and blood circulation.

In the Thai medicinal practices also we could see a holistic approach towards the human body. According to Thai philosophy, human life is a combination of three essences: body, mind and sprit. The three branches of medicine are each associated with one of these essences. The Thai medical tradition recognizes diseases caused by germs, allergies, environmental factors, heredity, and emotional or psychological imbalance[26]. When the three essences are balanced, the human organism enjoys health and well-being. The imbalance of the three essences causes this natural health and immunity to break down, leaving the organism vulnerable to disease[27]. Maintaining balance of the three essences is therefore the primary focus of traditional Thai medicine. .

Many of the historians admit that the Indian medical system has for at least 500 years been used as an explanatory model by the Thais. It has contributed to the indigenous ideas to several important Thai medicinal practices. It further admitted by the anthropologist's one could see many similarity between Ayurveda and Thai medicine and some Thai concepts (such as tridosha and nadis) even share the same names as their Ayurveda counterparts. Therefore, at least a cursory glance at the Indian traditions is unavoidable in any work on Thai medicinal traditions.

[25] Curcuma, lemon grass, kaffir lime, camphor etc.
[26] http://www.taomountain.net/traditional-thai-medicine/thai-ayurveda.html
[27] *Ibid*

Yet Harald "Asokananda" Brust, the foremost Western writer on Thai massage, rightly opined that the historical origins of Thai Medicine are shrouded in mystery:

> *'Despite what is known about Kumar Bhaccha, much of the origins of Thai massage and traditional Thai medicine still remain obscure. It is believed that the teachings of Kumar Bhaccha reached what is now Thailand at the same time as Buddhism as early as the 3rd or 2nd century BC. It is unknown whether there was any indigenous form of [medicine] in the region before that time. Equally unknown is to what extent Chinese concepts of acupuncture and acupressure (as well as other aspects of traditional medicine) had any theoretical and practical influence.... Nowadays it is impossible to definitively answer such questions, since for centuries medical knowledge was transmitted almost entirely orally from teacher to student following a teaching traditional also common in India."*

1.1.3. ***Srilanka:-***

Sri Lanka has a recorded history of about two thousand five hundred years[28]. During this whole period it has had its own system of medicine. It is not a static system of medicine, but has from time to time been influenced by forces.[29]

TK in Sri Lanka is mainly in the formalized systems such as Ayurveda, Siddha, and Unani, which have largely introduced into Sri Lanka from suthern part of the India. The earlier system of medicine that prevailed in

[28] www.viruallibrary-srilanka

[29] B. Wjjeyaratne ; traditional medicine in srilanka

Sri Lanka was desiya chikitsa or simhala vedakama[30]. The concept of 'Hospital' is first introduced by the Sri Lanka[31].

There are five plants, which according to folklore have been used for the protection of plants against disease. These plants have been studied for their pesticidal activity and found experimentally to have weak to moderate plant protection properties. It is possible that they were effective against the old varieties of pests but are unable to counter the more pesticide resistant varieties of pests found today. Their role could also have been that of a green manure rather than that of a pesticide[32]. So these kinds of environmental knowledge also include the traditional knowledge of the Sri Lanka.

But Sri lanka also facing the misappropriation of its TK by developed countries A recent example is a Sri Lankan plant[33], *Salacia reticulata*, long reputed and locally exploited for its anti-diabetic properties. The plant and a related plant found in Sri Lanka, *Salacia prinoides*, have been investigated in Japan and the United States for this activity and its hypoglycaemic constituents have been the subject of several publications[34] and patents by Japanese[35]and American[36] scientists, with no reference to Sri Lankan participation.

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[30] C.G. Uragoda "A historical background to traditional medicine in Sri lanka" from http://www.searo.who.int/LinkFiles/Regional_Health_Forum_c6.pdf accessed on 12.2.09

[31] http://oaks.nvg.org/ys6ra4.html accessed on 12.2.09.

[32] Vijayakumar, " Systems and national experiences for protecting traditional knowledge ,innovations and practises-srilanka" ;UNACTAD expert meeting on Systems and national experiences for protecting traditional knowledge ,innovations and practises ; 30 oct- 1st nov. 2000; Geneva.

[33] Supra n, 32.

[34] Yoshikawa *et al.*, 1998a, 1998b, 1998c; Shimodo *et al.*, 1998.

[35] Yamahara, 1999)

[36] Inman and Reed, 1997

1.1.4 ***India: -***

The concept of medicine disease, and practice may be said to have been developed in ancient and mediaeval India through a number of successive phases, however there was no distinct line of demarcation between the stages. As already mentioned even in India also superstitious notions and crude traditional practices were attached with the concept of diseases.

The evolution of traditional medicine can be divided in to following stages.

1.1.4.1 <u>The period of supernatural theory</u> :-

This period is considered to be "dark age" of the human civilization. Early stages of this period man more or less imitate animals in treating his illness i.e. liking, sucking blowing and covering with mud etc. but in the "stone age" he invented tools consequently he started incision, trepanation, blood letting, amputation, and other surgical operations. This period had witnessed witch craft, magic, sacrificial offerings, weird dances etc as a method of treating diseases.[37] Most of the medicinal practices were attached with rituals of the community. As in all other civilization pre-vedic period Indians considered root cause of the disease is the wrath of God, entry of demons or evil sprit etc. But it is to be noted that this attaching demons to a particular disease paved the way to develop the germ theory of medicine. However in short with regard to medicinal practice this age is applied less reason and more assumptions.

[37] Manjumdar ;races and culture of India – anthropology and primitive medicine p 433

1.1.4.2 Usage of mantras and vegetable substances:-

In the Vedic period medicine was developed as an adjunct to religion. This changed the concept of disease and its treatment however there where some shadows of mystic faith, magical and ritual rites existed. Most of the treatments were followed by chanting mantras, fasting, giving offerings and so on. But the notable change in this period was an increasing use of vegetable products, animal substances as helpful agents for treating diseases.

There were some interesting instances of treatment is mentioned in *kaushika sutra* the treatment of patient suffering with jaundice by yellow bird tied near the bed of patient, treatment of dropsy by cold water on the body of the patient[38]. But one could not unnotice the classification given by the Athrvaveda for drugs[39] and diseases[40]. Humoral theory of disease originated at this stage. The three humours vata (wind), abhra(phlegm) and susma (bile) in their state of equilibrium were recognized the basic factors for health; and increase and decrease of anyone or more of these in resulted in diseases. it also gives an elaborate account of the symptoms of many diseases.

[38] Kaushika suthra 26, 14-21, 25-37, 32,14-15 ;31,7.
[39] Two classess ayusyani (drugs which used for prolonged life); bhaisaijyani(those which cure diseases)m
[40] External and internal:possession by demons or sprits, wrath of gods, change of season, worms, loss of humoral bablnce, heredity, contagion, and unwholesome food.

1.1.4.3 Period of Ayur Veda

This period Indian medicinal knowledge reaches its highest peak of glory. This is also known as the age of the ayurveda (knowledge of life). The two very well known ayurvedic treatises, the caraka samhitha and the susrutha samhita, were composed during this period. These incorporated the highest wisdom of Indian medicine and formed the basis of all subsequent compilation on the subject. Ayurveda discusses eight branches of medicine. susruta samhita disscuss about the origin and classification of diseases. Similarly caraka samitha disscuss about the method of diagnosis. In those day treatment of medication includes eye drops, medicinal cigars, nasal medication etc. ayurveda more concentrate upon the preventive approach. The old texts given a detailed description of surgical instruments also. It is interesting to note that the embryonic growth in the womb from the time of conception to the date of delivery has been described in some detail in caraka and susruta, which does not differ much from that of modern medical texts. [41]The *Atreya Samhita* is perhaps the oldest medical book in the world; it survives from Taksashila University, which dates back to the middle of the first Millennium BC. The *Atharvaveda* lists eight divisions of Ayurveda: internal medicine, surgery of head and neck, ophthalmology, surgery, toxicology, psychiatry, pediatrics, gerontology or science of rejuvenation, and fertility[42]

[41] Caraka samhitha ,XV, 3-5; susrutha samhita iii, 14- 19

[42] http://www.indianscience.org/essays/t_es_herbal_medicine.shtml

1.1.4.4 Development Of Tantras, & Yoga,:-

Tantra and yoga developed in this age. According to tantra the body can be made immortal by the use of mercury and its preparations feeling of patient's pulse as a method of diagnosis of diseases was possibly first introduced during this period as discussed in a text of Ayurvedic medicine, cikitsatilaka (twelfth century A.D) by Tisatacarya [43]

1.1.4.5 Development Of Sidha, Pranic Healing Etc:-

Apart from the eight classical branches of Ayurveda, development of Unani, Sidhha, Pranic healing aroma therapy or Reiki etc are the other contribution of this time. These are the other traditional medical sciences, which came into India from other countries and developed into a separate stream of medical science.[44]

1.1.4.6 Evolution of traditional medicine in Kerala:-

Kerala has an unbroken tradition of Sanskrit learning. This knowledge of Sanskrit enables the healers of Kerala to interpret the auyrvedic system accurately and get a proper insight. Earlier day only Brahmins can perform the fire sacrifices or yajnas as they were done during the Vedic times and pronounce the Vedic chants the original way. Earlier Kerala had 18 city – state and each state had a family that practiced ayurveda and other traditional healing systems in order to look after king and his subjects. These medical practitioners were known as Ashtavaidyans, literally

[43] Kutumbaih "The pulse in Indian medicine" ,Indian journal of history of medicine, Vol.12, 1967, p.11-12.
[44] http://india.mapsofindia.com/culture/indian-medicines/alternative-therapy.html

translated to doctors trained in the 8 branches of ayur vedic medicine. Thus 18 families of ashtavaidyans existed in the days of yore. They were the torchbearers of the 5000-year old traditional medicinal practice of kerala. However since they were engaged in surgery and were likely touch blood, they were not allowed to intermingle with other Brahmin families. This led to a lot of inbreeding within these 18 families and consequently, a decline in their fertility. Thus the ashtavaidyans came to be reduced to 8 families. Among these eight families ,six families are still practicing today[45]. Mainly the transmission of knowledge happened through, inter and intra marriage between the communities or as a 'means of warfare' they transmit these knowledge form one to other.

1.2 DEFINITION AND SCOPE OF THE TERM TRADITIONAL KNOWLEDGE.

There is no specific definition for the word traditional knowledge. But many debates and discussion have taken place in various platforms to explain the meaning of traditional knowledge[46].This lack of definition is not due to ignorance. It is a deliberate and wise omission because of the vastness of the concept. The laws in India refrain from defining traditional knowledge, Even the TRIPS agreement and the Convention of Biological Diversity, 1992 have any clear definition on traditional knowledge. The basic feature of traditional knowledge is that it is not created or produced systematically but it is created or produced collectively or individually in relation to one's cultural and

[45] http://www.indianetzone.com/2/kerala_ayurveda.htm
[46] Sreenivasulu N.S. "intellectual property Rghts", Regal publications, Newdelhi -110027

traditional environment. Besides, traditional knowledge represents cultural values of a particular group[47].

The term traditional knowledge started using after 1977, till 1977 "folklore" was used. The term "traditional" does not imply that it is old or un technical in nature, but tradition based; it reflects the information that people in a given community have developed over time based on experience and adaptation to a local culture and environment. The term "traditional" refers also to the way of knowledge is fashioned, conserved and circulated. Further traditional knowledge is traditional only to the extent of its creation and its use. These are part of the cultural traditions of communities and empirically tested its effiency through generations. "Traditional" knowledge is being created every day, it is evolving as a response of individuals and communities to the challenges possessed by their social environment. In its use, traditional knowledge is also contemporary knowledge. [48]. It is now recognized that TK is not static or fossilized. Every successive generation creates knew knowledge.

It is intimately linked to the biodiversity of local biotopes. Traditional communities have conserved but are not necessarily collective. Given the highly diverse and dynamic nature of traditional knowledge, it may not possible to develop a singular and exclusive definition of the term. The concept of TK is conceived rather broadly, similar to the concept of invention.

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[47] Ibid

[48] B.N. Pandey , " biological diversity bill, 2000 :traditional knowledge and intellectual property rights", central India law quarterly ,vol.15, p at 230

So the scope of the TK is not limited to any specific field of technology or arts. But the entire field of human endeavor is open to inquiry by traditional methods and the full breadth of human expression is available for its transmission.

1.3 TRADITIONAL KNOWLEDGE HOLDERS AND KNOWLEDGE OF THE COMMUNITY

The Yanadi tribe in Southern India is considered as experts in snake catching. They know the use of 22 wild species as antidotes for snakebites and they often sell the roots/rhizomes of plants as antidotes along with other medicinal herbs in the nearby towns and cities. This is a glaring example of the knowledge of that particular tribal community. In the similar way there are over 53 million tribals, belonging to 550 tribal communities in India. And there are no statistics available on the kind of medicinal and other wonders which all of these tribal communities combined together may hold[49]. The basic difference being in the fact that traditional knowledge is largely in the public domain except for some specific knowledge related to some medicinal plants which is vested with only the traditional healers in a community and is transmitted to a few in the next generation

The issues of the economics of community knowledge are truly complex. While it is true that many indigenous cultures appear to develop and transmit knowledge from generation to generation within a system, individuals in local or indigenous communities can distinguish themselves as informal creators or innovators, separate from the community.[50] Furthermore, some indigenous or traditional societies are reported to

[49] Ankur Gupta, "Traditional Knowledge or Capitalist Goldmine?" Combat Law, vol.4, issue 4 , 2005
[50] http://stp.unipune.ernet.in/ipr/tradi.htm

recognise various types of intellectual property rights over knowledge, which may be held by individuals, families, lineages or communities[51]

The issue of finding out who is the holder of a traditional knowledge in a specific community is a difficult task. There is certain traditional knowledge where a particular family only holding it , though the entire community has the information about that knowledge but this particular family only invented and practising that. In such cases traditional knowledge holder will be that particular family. Similarly in some community a particular inventor or developer has a distinctive element of creativity possesses. Most of the time IP protection rarely acknowledges these grass roots inventors. They gave recognistion to the community only.

Present scenario the term traditional knowledge holders refers to the community. often these communities have unwritten customary laws which govern the access and use of traditional knowledge. All the members of that community have an access to that traditional knowledge and make use of it. Attempts are being made presently to define the community, as the benefits of commercial exploitation should reach the holders of traditional knowledge[52]. The relation between traditional knowledge and community is however dependent upon the nature of traditional knowledge. Therefore the significance of the community can be diminished in the context where the TK is commonly known to the community or where the traditional knowledge is held by individuals or members of families. Therefore there is no complete convergence between the interests of local community holders and those of local experts and traditional knowledge holders.[53]

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[51] Ibid

[52] T. Ramakrishna, Biotechnology and Intellectual Property Rights, 2003 , CIPRA, NLSIU , Bangalore, p 73.

[53] Ibid.,

CHAPTER –II

TRADITIONAL KNOWLEDGE AND ITS PROTECTION UNDER CONVENTIONAL IPR REGIME

Even today many of the communities are dependent upon and following their wide pool of traditional knowledge system. It is not a mere system of knowledge but the integral part of their life. Their entire development and well being is completely relying upon this system of life. Its practical value is increasing day by day. In some cases TK is directly beneficial to the society but in some other cases it indirectly. Some of the examples are recent agreement would give traditional healers in Samoa a share of the benefits from a new AIDS drug drawing on their knowledge of the "Mamala" tree[1]. Similarly the knowledge related to the environmental planning and resource management of the tribes in Canada is considered as valuable. So now the global community is looking towards the traditional knowledge owned by the tribal communities all over the world. But the most unfortunate thing is that many of the time commercial exploiters taking patents and exploiting commercially without acknowledging this indigenous communities properly. Therefore protection of TK is an urgent concern to address by the national and international communities. In this Juncture Intellectual property protection and TK raises a numerous questions with regard to the manner and method of the protection of TK.

[1] Book let issued available at www.wipo.int pub 920.pdf accessed on 12.2.09.

2.1. NEED FOR PROTECTING TK

The WHO estimated that 80% of the population of developing countries relies on traditional medicines, mostly plant drugs, for their primary health care needs[2]. Since it is non-narcotic and having no side effects, Demand for medicinal plant is increasing in both developing and developed countries. In most of the developing countries Traditional health care system is the one which easily available at affordable prices and sometime the only source of health care available to the poor.

Medicinal plants play an important role in the medicinal preparation of health care systems. The Indian Systems of Medicine, viz Ayurveda, Siddha, Unani and Homeopathic system chiefly use plant based raw materials for most of their preparations and formulations. Modern pharmacopoeia also contains at least 25% drugs derived from plants and compounds isolated from plants[3].

Similarly farmers and livestock keepers have improved and nurtured diverse varieties of crops and domesticated animals over generations. This has been invaluable to food security and providing clothing, health care, and shelter. They are playing good role conservation wild biodiversity also. Eg. 'Sacred groves', some thousands of years old, dedicated to a local deity[4] . So their utility and importance is also acting as a ground for protection.

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[2] The report of the Task Force on Conservation and Sustainable use of Medicinal Plants; published in March 2000.

[3] Ibid.,

[4] Tejaswini Apte , A Simple Guide To IPR, Biodiversity And Traditional Knowledge, 2006, Kalpavrish, Grain & IIED, Pune /Newdelhi

Apart from its utility concern, there is one more reason which compel the global community to think for the protection of TK. i.e., Bio-piracy[5] which can include either or both of the following

- Obtaining IPR gain monopoly control over biological resources, related traditional knowledge, or commercial products based on these resources or knowledge, without the consent of, or any benefits going to the original holders of the traditional knowledge.
- Commercially exploiting biological resources or related traditional knowledge without the consent of, or any benefits going to, the original holders of the resources/ knowledge.

With the emergence of new technologies in applied biology, as for example –improved methods of bioprospecting, the possibilities of ex-situ utilization of traditional knowledge are increasing. Traditional knowledge and especially traditional medicine has the potential of being translated into substantial and humanitarian benefits by providing commercial leads for development of useful products and processes. This also catalyzed bio piracy. So it is high time that we should think of protecting the valuable traditional knowledge associated with medicine.

2.2 WHAT IS MEANT BY PROTECTION

The term "protection" itself implies different connotation in different parlance. It depends on how one person is construe it, what his intention is, and what he wants to

[5] Supra n, 4

protect. So the issue of protection cannot be looking into one perspective, it should look into in its entirety.

Therefore protection of traditional knowledge may includes, conservation of that knowledge, development of that knowledge through propagation and continues exercise of it, while using that knowledge it should be in a sustainable manner, and it should benefits the interest of the holder/holders of the traditional knowledge. However, it does not mean that these are the components of the term protection. We should afford protection according to needs and wants. So what protection in one country may not be affording adequate protection in other country if the later is blindly following the former. It will depend on our objectives; and what exactly we want to defend.

But it is to be admitted that in every legal system, the issue of 'protection' should include at least protection from the unauthorized use by third parties of the protected information. On the other hand, the "Protection" is also means to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities that have developed and applied it. The new products and technologies developed by multinational companies can be protected by patents and other intellectual property rights, while 'traditional knowledge', accumulated in indigenous communities over generations, is generally unprotected by modern legal systems, and may be used freely by all[6]. This perceived inequity has led to vociferous calls for the protection of 'traditional knowledge', to provide a counterbalance to the rights of companies in new technology.

[6]http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Protecting_Traditional_Knowledge.pdf accessed on 19. 3.09

Increasingly, such calls are given credence and have built up political momentum, to the point at which governments may find it necessary to act.[7]

Further, the protection also promotes self-respect and self-determination. In the intellectual property, protection means protecting property over something in a specific way, but in ordinary usage it has much broader meaning. This has proved particularly problematic in the discussions on protecting traditional knowledge at WIPO[8]. Most of the time when we talk about the protection of TK, our focus will be on freezing and preserving the knowledge that exists now. But this is unfortunate, we should think beyond that. As already stated, TK is not static, it is evolving in nature. So protection which we are giving should be a nature of one which will not hinder its natural development and free dissemination of TK.

2.2.1 ***Nature of protection:-***

Nature of protection can be divided into two. One is positive protection, which means giving TK holders the right to take action or seek remedies against certain forms of misuse of TK ; and the second is Defensive protection, which means safeguarding against illegitimate IP rights taken out by others over TK subject matter. Though some are of the opinion that these are different form of protection, yet it is admitted that these two approaches should be undertaken in a complementary way. A protection which involves these both will give better protection to the traditional knowledge holders.

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[7]Supra n 6

[8] Good ideas turned bad? a glossary of rights related terminology , grain seedling- biodiversity, rights and livelihood , January 24

According to WIPO Any system of positive protection of traditional knowledge must provide for[9]:

- Recognition of value and promotion of respect for traditional knowledge systems.
- Responsiveness to the actual needs of traditional knowledge holders.
- Repression of misappropriation of traditional knowledge and other unfair and inequitable uses.
- Protection of tradition based creativity and innovation.
- Support of traditional knowledge systems and empowerment of traditional knowledge holders.
- Promotion of equitable benefit sharing from use of traditional knowledge.
- Promotion of the use of traditional knowledge for a bottom up approach to development.

Similarly any system of defensive protection[10] of traditional knowledge must provide for:

- The criteria defining relevant prior art apply to the traditional knowledge.
- A mechanism to ensure that the traditional knowledge constituting prior art is available and accessible to search authorities.

Importance of comprehensive approach of protection of TK will understand better by analyzing the following case studies.

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[9] Supra , n.1
[10] Ibid,.

2.2.2 ***case study- 1:- patenting of turmeric***

This is the glaring example for the defensive protection, where in which two US based Indian were approached USPTO for granting patent on Turmeric. They claimed that from their invention they had found that turmeric has wound healing capacity. Subsequently they got patent on Turmeric. But later CSIR, New Delhi , India challenged that patent on the ground that there is no novelty on the part of the invention as it already known in the public domain of India. Since time immemorial Indians are using turmeric as cosmetic, wound healer etc. Furthermore they located 32 references where turmeric is mentioned for its wound healing property making it evident that the finding was not new and well- known since years. Patent on turmeric was proved invalid on grounds of novelty and inventiveness so the patent was revoked.

This particular case assumes importance because it was the first time that a patent based on traditional knowledge of a developing country was challenged and the patent was revoked by US patent and Trade mark office[11]. Although the case of turmeric was a milestone in the whole series, most of the countries have witnessed misuse of knowledge in one way or the other[12].

2.2.3 ***Case study -2:- story of jeevani***

In 1987, a medicine named jeevani was developed from trichopus zeylanicus (aryogya pachha) plant, found in tropical forest of southwestern India, which

[11]" Who owns traditional knowledge" Suman sahai, ICFAI journal of intellectual propertyrights, vol.vI ,no 3 2007

[12] Ibid

is derived from arogyapachha plant and is traditional knowledge used by kani tribe of thiruvanathapuram district in kerala[13]. It helps in improving atelatic performance, mental alertness and work output. Scientist at TBGRI Kerala, India under took research to isolate active element in arogyapachha plant. They filed a patent application in India and not in other countries.[14] In 1995 TBGRI negotiated technology transfer agreement to other interested parties on payment of license fees which is shared in a fifty- fifty proportion with the tribe. Now this tonic is manufactured by major ayurvedic companies in Kerala.[15] The prime concern of the tribe was to evolve a mechanism through which they can receive the funds keeping this in their mind they established 'Kani samudaya kshema trust' to promote both welfare of kanis in Kerala and also to ensure sustainable use and conservation of biological resources[16]. Though in the initial stage there was a dispute in distributing the benefits arrived from the TBGRI but ultimately they resolved to a larger extent.

Whether the kanis are entitled to the patent. If yes, whether as inventor, or joint inventor or traditional healers?

- The proportion of the benefits awarded to the Kanis in light of the initial work by the kanis themselves, and subsequently the TBGRI who undertook the task of identification and isolation of compounds and other related processes?

[13] anu jindal " IPR and Protection of Traditional Medicine" icfai journal of intellectual property law; vol 6; no 3; 2007;p 31-38
[14] Ibid .,
[15] Ibid.,
[16] Ibid.,

- The high demand may result in an increase in the rate of cultivation of the plant which may cause ecological and environmental concerns?
- Should programs for the sharing of benefits be managed at the level of the individual, sub-clan, clan (Kanis), state (Kerala) or nation (India)? [17]

2.2.4 ***Case study -3:-patent of ayahusca***

Ayahusca is drink made by shamans, an indigenous Amazon basin Tribe. Using a plant called Banisteriopsis caapi , ayahusca drink was made and used in religious and healing ceremony, which was traditionally administered by traditional healers. This plant has been used by healers and religious leaders throughout the Amazon for generations and since time immemorial. Shamans have used ayahuasca to treat sicknesses, contact spirits, and foresee the future. Many indigenous Amazon tribes also view the plant as a sacred symbol of their religion.

In 1986, Ayahuasca was patented by Loren Miller, an American scientist and entrepreneur[18]. The patent for the drink was granted by USPTO in 1986 and applicant named it Da Vine. The patent was subsequently revoked in 1999, as there was no novelty and inventiveness. But the applicant convinced authority and got patent on it consequently the natives and the tribal leaders of the learnt of the existence of such monopoly right granted several years after it was so granted. Antonio Jacanamijoy, the leader of a council represented more than 400 indigenous

[17] Suman sahai, ICFAI journal of intellectual propertyrights, vol.vI ,no 3 2007
[18] http://www.rkdewan.com/articles-traditional-knowledge-ip-rights.jsp , The Ayahuasca Patent Revocation: Raising questions about current US Patent Policy, 2001 by Boston College Third World Law Journal

tribes and groups in South America applied for and obtained a rejection of the ayahuasca patent from the U.S. Patent and Trademark Office. And finally rejected the patent[19]

From the analysis of these cases we could come to a conclusion there is a need for protection of TK, as it is vulnerable to the biopiracy. Some time it is associated with their beliefs or

2.3 IPR AND TK

In the beginning, property includes nothing more than corporeal property that is to say the right of ownership in a material object, or that object itself. In this sense a man's land, chattels, shares and the debts due to him are his property.[20] The owner of a material object is he who owns a right to the aggregate of its uses. It is considered that the state and law came into existence only for the protection the right of the property[21].

In the modern era the meaning and the scope of the property has a very wide meaning. It could be either tangible or non tangible. As time passes man considered the contribution of human brain can be considered as his private property of that man and the right attached with this property is termed as intellectual property rights.

IPR laws exist in most countries of the world. The concepts of IPR are based on the idea that innovation is the product of genius of individuals such people by sharing the fruits of their genius with society, are deemed to be deserving of economic rights granted by the state on behalf of the society. These economic rights are collectively known as IPR. It offers

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[19] Supra n, 17.
[20] S.R.Myneni; Law Of Intellectual Property , 3Edn; Asia Law house; Hyderabad ; P,2.
[21] Ibid.,

the protection through different types of legal arrangement. The conventional IPR regime consists of protection through patents, copy right, trademark and designs. So it is necessary analyze the existing traditional IPR protection with regard to traditional knowledge.

2.3.1 *Patents:-*

A patent is a legal certificate that gives an inventer exclusive right to prevent others from producing , using, selling, or importing the invention for a fixed period utility (usually 17-20 years) legal action can be taken against those who infringe the patent by copying the invention or selling it without permission from the patent owner[22]. Since the intellectual property rights are economical rights, its more inventor or author centric. Each patent application should follow the three criteria. i.e., novelty, utility, and non obviousness. Though the nature and scope of these three requirements vary country to country, yet the awarding of patent is based upon these three requirements. This makes the protection of TK under patent become a difficult task.

2.3.1.1 Criticism

Problem of protection starts from the initial stage itself .i.e. lack of an individual owner. Since the indigenous knowledge system is based on the creation of a work by the community as whole, there cannot be granting of absolute monopoly to an identifiable sole individual. The works have been created by their forefathers, and

[22] Darell A. Posey etal.; Beyond Intellectual Property Toward Traditional Resource Right For Indigenous People And Local Communities ;1st Edn.; international development research centre; Ottava; Canada; p.76.

worked upon by subsequent generations. The work has been subject to constant innovation and "improvement". But this improvement takes place in the very course of life, hardly noticeable, but never recorded and noticed as such, unlike strict parameters of IP[23]. Thus none can be identified as a sole inventor, author of the intellectual property or the knowledge created. So the question of who is the inventor or author is a tight spot to answer.

Another problem is that the **issue of Novelty**. The term 'Novelty' implies the invention should be recent and original, but perhaps most importantly it should not already be known (in the public domain)[24]. Since a substantial collection of traditional medicinal knowledge is "ancient", passed down from generation, this can not be considered as novel. Traditional knowledge is already known to the public or it's the part of the prior art. So in short TK is fail to meet the requirement of novelty under patent law. But it is to be noted that assessing the novelty requirement or whether an invention is a part of the prior art is varied from country to country. Industrial countries like USA lenient approach towards the protection of TK. According to the US law novelty of an invention will go only if there is a written publication of that invention. So oral publication cannot loose the novelty of that invention. This created lots of dispute between interest of the TK holders and the developed countries.

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[23] Supra n., 17.
[24] Supra n., 21.

Another problem is meeting the **requirement of "inventive step" or "Non obvious".** It means the invention not obvious to a person skilled in the technology and more inventive than mere discovery of what already exist in public domain. The invention must be disclosed to the patent examiners in a detailed way that would enable a skilled technician to make and use it. Most of the traditional communities are illiterate. It is difficult for them to explain "their invention" in the parameters of "modern scientific language". So they fail to prove the criteria of inventive step. Furthermore an inventive step is determined by making a comparison with the prior art base. The problem that indigenous people would have is establishing that because of the traditional knowledge that existed, the scientific or commercial use to which the knowledge has been put to is obvious therefore uninventive.[25] So as far as the TK holders are concerned meeting of these requirements are hard nut to crack. More over this excludes the patenting of naturally obtained genes, organisms or patent. But once you isolated compound and formulated a new product, then that could be patentable. In short, any thing which is in the crude form is not patentable.

But on the other hand companies can obtain patents based on traditional knowledge. Companies have investigated useful

[25] Gray, Stephen, "Vampires Round the Campfire: Indigenous Intellectual Property Rights and Patent Laws", (1997) 22 as cited in http://74.125.153.132/search?q=cache:aiSHveUsJtcJ:www.apjslg.com/articles.aspx%3Fd9720ee9-d733-4076-975eaa8bb0817d0c+protection+of+traditional+designs+of+the+indigenous+communities&cd=1&hl=en&ct=clnk&gl=in accessed on 12.2.09

attributes of a biological substance known to a traditional community. Although normally a product patent cannot be obtained for a naturally occurring organism, chemical or gene, in some industrial countries patent can be obtained for one that has been altered in some way[26]. Therefore, after isolating the active principal of a substance, the company can modify it or use it n the design of a new synthetic compound that may be toxic than the original substance. Such an invention can be patented by the companies[27]

The third requirement[28] of the patent law is that **"utility" or "capable of industrial application"** which means mere discoveries or information in per se not patentable unless and until it translated in to a commercially exploited form or in useful form. "The mere existence of genetic resources on land they own or formerly owned will not give them any intellectual property rights in these resources, should they turn out to have some scientific or commercial value. In order to gain protection or to prevent others from gaining it, the indigenous people would have to 'discover' the resources, and put them to a new use with commercial significance".[29]

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[26] Supra n, 21

[27] Ibid.,

[28] These requirements are commonly seen in all jurisdiction. 35 United States Code Sec 102 onwards; Secs. 1-4, of the Patents Act 1977, U.K.; Sec. 2 (j) of the Indian Patents Act of 1995.

[29] Blakeney, Michael, "Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective", (1997) 6 European Intellectual Property Reports, p 298 as cited in "patent and the rights of indigenous people" Megna surya kumar http://ipr.indlaw.com/display.aspx?276

Since TK are diverse in nature, some part of the Traditional knowledge may get patents apart from these difficulties in such cases the following difficulties will occur

- **Complexity and cost of drafting and prosecuting patent applications**

Apart from these theoretical problems, there are some practical difficulties also existing in protecting TK under patent law. I.e. The complexity and cost of drafting and prosecuting patent applications, is beyond the means of the holders of traditional knowledge.

- **No effective legal support**

One of the biggest threat is that obtaining patent by the big companies by copying the traditional knowledge of the community. The community might not know about it, and even if it finds out, legal action can be very expensive. Whereas corporations have their own lawyers and financial resources to provide effective legal support, local communities rarely have such resources or advocates. Even if a case does go to court, the company may well succeeded in convincing the court that its product, use or process is sufficiently different from the original to constitute an invention[30].

- **Problem of licensing and negotiation**

Even if they wants to license it they have to negotiate with big corporation, for them specialized legal person will render advices in that regard where as in the case of indigenous communities do not

[30] Supra n,. 21.

usually have the financial resources to recruit such advice and are thus poorly equipped to determine the fairest proposals. So there is lack of parity of powers.

The UNCTAD also expressed the above-mentioned constraints with respect to the protection of traditional knowledge in the following terms[31].

"While individual TK holders could in theory acquire a patent, it is generally the case that TK is passed on orally from generation to generation and evolves incrementally. Thus, it would be difficult to meet the criteria of novelty and inventive step. Second, TK tends to be generated collectively to the extent that no inventors are identifiable. Indeed the source of much TK cannot be traced to a specific community or even to a geographical region. Even if these obstacles were somehow overcome, most traditional communities do not have the resources to file patent applications or to take legal action to prevent patent infringement."

2.3.2. ***Copy right:-***

Copy right law is intended to protect authors by granting exclusive rights to sell copies of their work in whatever tangible form is being used to convey their creative expressions to the public. Copy right gives authors legal protection for the following types of work (i) Literary works (such as books , film scripts, and even private correspondence) ; (ii) Dramatic and musical work (such as plays and music compositions recorded in the form of musical notations); (iii) Artistic works and works of applied art (such as paintings ceramic, carvings). (iv) Maps and technical drawings; (v) Photograph works; (vi) Motion pictures and sound

[31] Supra n, 17 Each of these constraints was identified by WIPO in fact-finding missions conducted in 1998 and 1999 on the intellectual property needs and expectations of holders of traditional knowledge

recordings (such as movies, documentaries, and interviews) (vii) Computer programs and databases.

Example : 1

There is one aboriginal community living in the Malaysian rain-forest named, Teminar community , their major technique of healing involves singing trance dancing ceremonies . They make tunes and text for each diseases, it is their belief that during the ceremonial singing as a treatment, the lost soul should be shown the right path and led it back to home[32]. This community could avail protection of their medicinal healing practice under copyright regime as it is in the form of music. But we should not forget that majority of the traditional healing practices are neither codified nor involves any music or particular expression . so its ambit is not that wide enough to include traditional medicinal practices.

Copy right protection covers only the expression of ideas not the idea as such, which are not required to be novel at all. Copyright protection gives owners exclusive right over it for his life time and 50 years after his death. In the case of sound recordings, copyright is usually conferred for 50 years and is available to the person or company responsible for making the recording.

Indigenous people may be concerned about outsiders reproducing their arts, crafts, songs, and designs without permission and either neglect to acknowledge the source of the creativity or pass off work as genuine indigenous art when they are not.

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[32] Marina Roseman; Healing sound from the Malaysian Rainforest: Teminar music and medicineberkely losanjel , London ,university of California press, 1993, p 234

2.3.2.1 Criticism

There are some limitations on the copy right law as an IPR tool to protect TK. One of the main limitation is that generally Copy right are assigned to individuals or companies, where as indigenous people are more likely to desire protection of the rights of the community or tribe. So, in such circumstances, conferring authorship becomes a dilemma. Another problem is that the protection of TK should theoretically be in perpetuity, but in contrast copyright protection is fixed for a certain period. This "duration specific nature" of copyright is also making problem.

Another constraint of copy right is that it covers only "expressions" not "ideas". So even a person can absorb idea from Traditional knowledge holders and expressed in a similar way. Furthermore, among some indigenous group, many expressions their TK are not fixed but are passed on orally from generation to generation. And constantly developing in nature. This excludes such expressions from eligibility for copyright protection

2.3.3 ***Trademark:-***

Distinctive signs (trade marks, collective marks, certification marks, geographical indications): traditional signs, symbols and terms associated

with TK have been protected as marks, and have been safeguarded against third parties' claims of trade mark rights

Example :- 2

For instance, the Seri people of Mexico, faced with competition from mass production, registered the *ArteSeri* trademark to protect authenticiron wood products that are produced by traditional methods from the *Olneyatesota* tree. Conservation of this unique species of tree was also a factor in protecting the trademark. Also in Mexico, the appellations of origin *olinalá* and *tequila* are used to protect lacquered wooden products and the traditional spirit derived from the blueagave plant, both products of traditional knowledge that derive their unique characteristics also from the indigenous genetic resources of these localities[33].

2.3.3 1 Criticism

Trademark is only protecting a part of the TK. It covers a limited part of the TK. Moreover most of TK will not get protection under trade mark since it doesnot carries any specific form of mark or signs. Hence the trademark law is also fail to give a comprehensive protection to the traditional medicinal knowledge.

[33] Supra n, 21

2.3.4. ***Trade secret***

The law of confidentiality and trade secrets: this has been used to protect non-disclosed TK, including secret and sacred TK. Customary laws of communities often require that certain knowledge be disclosed only to certain recipients. Courts have awarded remedies for breach of confidence when such customary laws are violated.

Example :- 3

A group of North American indigenous communities, the Tulalip Tribes, have developed Story base, a digital collection of their TK. Some of the TK may be disclosed for patent review. Community leaders identify other information as for use exclusively within the Tulalip community, according to customary law; the latter is protected as undisclosed information. Digital repatriation projects that involve the restoration of indigenous knowledge to original communities often need to apply confidentiality carefully to comply with customary law constraints on access to the knowledge.

2.3.4.1 Criticism

Only that part of the TK can be protected through trade secret which has possess commercial value and competitive advantage. Main limitation is that most of the TK are in public domain, hence it no longer regarded as trade secrets. Another limitation is its ambit is also very limited. Yet, many scholars are of the opinion that most of the traditional medicinal knowledge are not in public domain, but in private domain, therefore it has not lost its secret nature, hence the

community can go under trade secrets for those part of the TK which fulfills the criteria's of Trade secrets laws. However it will not address the address problem in its entirety. When it comes to the protection traditional medicinal knowledge as such, trade secret also fails to provide a comprehensive protection.

2.3.5.***Designs:-***

Industrial designs are defined in the Paris convention as the ornamental or aesthetic aspect of a useful article and may consist of the shape, pattern or colour of the article. For example the pattern on an article of clothing or pottery could be protected. The designs must be original and reproducible by industrial means. The period of protection is not indefinite but may be for 5,10,or 15 years upto a maximum of 25 years. Like trademark registering a design is cheaper and less time consuming than applying for a patent. It also gives owners the right to take legal action against infringers.

Example:-4

In India there are so many tribal communities, make articles which has distinct form of design and shape. Many of them has high commercial value too. The glaring example of it is soliga tribal communities in the northern part of the Karnataka. They are famous for their pots making ability.

2.3.5.1 Criticism

But when it comes to the protection, design law has lots of limitation which is inherent in nature. Main limitation is that protection afforded by design law is duration specific. Other limitation is it protects individual works. With regard to the protection of traditional medicine, designs are not adequate enough to protect it, since it has no specific design, shape or style.

2.3.6 ***Geographical indication***

Certain geographical names have acquired à lot of importance in commercial market, particularly with regard to the goods uniquely associated with such names. To prevent unauthorized person from misusing geographical indications, protection should be provided. It helps the indigenous sellers of those goods. Some of the examples of geographically protected goods are Aranmulla kannadi(mirror)[34], kanchipuram silks, dargeeling tea etc. While giving geographical protection to these goods, it will automatically helps both the consumer and the seller. Though geographical indication is providing protection to the TK certain extent, yet the majority of the TK can not be protected under it.

Since it covers only goods, any TK which is in the nature of service cannot be protected under it. Similarly it limited to certain geographical area

[34] The name 'Aranmula Kannadi' has been accepted for registration as a geographical indication under the GI Act, 1999 and published in the GI Journal No.3 dated 1 November 2004

only and most of our TK is not limited to one particular geographical area. Moreover it is difficult to find out the in which part of area this TK is originated.

Example:-5

Indian law protects geographical indication which identifies agricultural goods, natural goods, or manufactured goods as originating or manufactured in a region where a given quality, reputation or other characteristics of such goods is essentially attributable to its geographical origin. Therefore being a collective right, GI could be an interesting tool to protect medicines produced locally (from medicinal wild plant to processed product)many agricultural products have applied for registration as GI, as for example ***Njavara*** rice, the medicinal rice of Kerala. Ayurveda physicians use *njavara* in treating neuromuscular disorders, skin diseases and rheumatism.[35] .it got the geographical indication status on November 2007 along with palakkadan matta, another species of rice seen in the Palakkad district of Kerala. But the question is thus to see how and at which conditions GI permits legal protection of the product and gives right to the producers when commercialized in an open market with the risk of misuse.

2.3.6.1 Criticism

It has very limited sphere of application. Most of our traditional medicinal knowledge spread more than one region. Very few medicinal knowledge or practices carries specific

[35] http://www.livemint.com/2009/02/22222039/Farmers-yet-to-benefit-from-GI.html accessed on 25.2.09

feature because of origin. Apart from that, these medicinal practices can be practiced widely, irrespective of its origin. However, it is to be noted that GI is one of the most effective tool among the formal IPR tools for the protection of traditional medicine.

It was evident that traditional intellectual property rights were insufficient to and also ill equipped to protect the rights of the holders of traditional knowledge. The existing IPR systems are more focused upon concept of private ownership, individual innovation and rewarding of individual invention through economical terms. But in contrast traditional knowledge emphasize on collective creation and ownership of knowledge For many traditional communities, intellectual property is a means of developing and maintaining group identity and survival, rather than promoting individual economic gain.

There is a concern that IPR systems encourage the appropriation of traditional knowledge for commercial use, and that too without the fair sharing of benefits of the holders of this knowledge. They violate the indigenous cultural precepts by encouraging the commodification of such knowledge[36].

Another key concern shared by indigenous peoples worldwide is that the present intellectual property rights regime favors multinationals and other non-indigenous interests[37]. Most of the traditional knowledge holders are in the developing countries. So they cannot afford the patent fees at international level. In this way, the existing intellectual

[36] http://www.parl.gc.ca/information/library/PRBpubs/prb0338-e.htm accessed on 12..2.09
[37] Ibid.,

property rights regime is seen to help corporate interests and entrepreneurs lay claim to indigenous knowledge without appropriate acknowledgement or compensation for the communities who have developed that knowledge[38].

However it is to be remembered that Intellectual Property is not solely about rewarding the creator or the inventor, but it also looks at the recognition and respect for the contribution of the human creators. So we should think what should be the alternative step to end this catch -22

[38] Ibid

CHAPTER III

VARIUOS NATIONAL ATTEMPTS TOWARDS SUI GENERIS PROTECTION OF TRADITIONAL MEDICINAL KNOWLEDGE

WHO defines 'traditional Medicine' as "The sum total of all knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical mental or social imbalance and relying exclusively on practical experience and observation handed down from generation, whether verbally or in writing".[1] As we have already seen in the previous chapter that traditional form of protection is not appropriate for the protection of traditional medicine, then the alternate option is a sui generis protection for the traditional medicinal knowledge. Since there is a widely felt need that countries should make legislation based on national priorities to ensure the protection of traditional medicinal knowledge, international communities, national legislatures, and other organization started coming with different models of sui generis protection to the traditional medicinal knowledge.

3.1 MEANING OF THE TERM "SUI GENERIS"

Sui generis is a Latin word. It means "unique" or "special", leaving the *sui generis* system open to interpretation. It implies, especially in Spanish, something exceptional or strange. *Sui generis* offers a unique type of intellectual property right (IPR), which is different from the classical IPR, as is the case with the patent. The concept of sui generis legislation was first introduced in the negotiations on intellectual property within the GATT agreement,

[1] http://stp.unipune.emet.in/ipr/ipr_tm.htm accessed on 20.12.2008

as a way to grant intellectual property over plants instead of patents, which had met with widespread and strong rejection worldwide[2]. Initially it designed for the protection of plant varieties, but its ambit gradually extended to cover the concept like traditional knowledge and other cultural expressions. All sui generis models that could be tailored to the specific needs and circumstances of the Members are legally recognized systems. It is obvious that a sui generis system of protection appropriate for a developing country may require certain modifications in another developing country and these systems may not be even relevant to a developed country. These differences in ground realities and perceptions have made major contribution to the raging controversy on sui generis system[3]

3.2. EXISTING SUI GENERIS MODELS OF SELECTED COUNTRIES

An important element of sui generis law is that, contrary to the exclusive IPR awarded to the individuals or corporations, it offers a special type of IPR protection and benefit sharing system to communities which have either collectively created and incrementally improved an innovation or provided prior art underlying a new innovation, either process or product[4]. According to the TRIPs, the *sui generis* system should be "effective". However, it neither specifies which essential elements in a system nor specifies about any existing plant protection system as the model.

3.2.1. *Thai model*-

In Thailand, since about 10 years, there is a socio-political movement to recognize community rights and to protect traditional knowledge. This has facilitated the

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[2] Good ideas turned bad? a glossary of rights related terminology , grain seedling- biodiversity, rights and livelihood , January 24

[3] Suman sahai ; Why India should have sui generis ipr protection on plant varieties; available at http://www.genecampaign.org/Publication/Article/IPR/whyIndia_have_suigeneris_iprprotection.pdf accessed on 18.1.2009

[4] Ibid

enactment of an Act dedicated to the protection of traditional medicinal knowledge, since it was felt that 'mainstream' IPR legislation does not protect such knowledge sufficiently. In addition, the Thai Plant Variety Protection Act 1999 also contains provisions aimed at protecting traditional knowledge.

In 1999, Thailand enacted a law to protect TK in the field of medicines, The Act of Protection and Promotion of Thai Traditional Medicinal intelligence, B.E. 2542, 1999. This law establishes the rights of traditional healers to retain control over traditional medicinal knowledge through public registration[5]. The scope of subject matter protected under the Act includes 'formulas of traditional Thai drugs' and 'texts on traditional Thai medicine[6]'. The Act separates traditional medicinal knowledge[7] into two types: traditional medicinal formulations and medicinal herbs. Regarding the former, the law divides traditional formulations into three types[8] i.e., general formula, national formula, and personal formula.

The Act empowered that the Ministry of Public Health has authority to announce a certain formula of Thai TK as a "national formula", when it satisfied that it has a special medical value and significant benefit. The implication of such announcement is that it becomes the state property. So anyone who wants to use the national formula for

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[5] Act, B.E. 2542, Section 3

[6] Section 14:"Text on traditional Thai medicine" is defined as "the 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 on from generation to generation"
Section 3 "Formula of traditional Thai drugs" is defined as "a formula stated as the production process and ingredients which contain Thai traditional drugs, no matter what form the ingredients are." (Section 3).

[7] "Traditional Thai medicine" is defined as "the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention of, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production of traditional Thai drugs and the invention of medical devices, on the basis of knowledge or text that has been passed on from generation to generation."(Section 3)

[8] According to Section 16,"there shall be three types of traditional Thai medicinal intellectual property rights as follows: (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine (2) the general formula of traditional Thai drugs or general traditional Thai medicine document; and (3) the personal formula of traditional Thai drugs or personal text on traditional Thai Medicine."

commercial purposes must receive permission from the government official.[9] Besides that act stipulates that, whoever violates it has to be penalized.

A private person or individual can also registered under that[10]. The people who are eligible for registration of a "personal formula" include an inventor or developer of the formula or an inheritor of the inventor or developer of such a formula

3.2.1.1 Benefits of registration

The Thai Act does not include express provisions on conditions of protection. But the definitions in Section 3 contain certain conditions for traditional Thai medicine to be included in the scope of the Act. For example, the definition of the term "traditional Thai medicine" contains the qualification that the medicinal procedures, massage, production of traditional drugs or the invention of medical devices has to rest "on the basis of knowledge or text that has been passed on from generation to generation." passing of knowledge from generation to generation is acting as a condition precedent to get that status of traditional Thai medicine.

The Act affords exclusive rights by allowing the owner to use the registered personal knowledge for research and to sell and distribute any product developed or manufactured by using the registered medicinal formula. However, the law lays down certain limitations to the exclusive rights. The legal rights may not be enforced against: (i) academic research and experimentation without commercial interest, (ii) preparation of

[9] . The Ministry of Public Health is authorised to adopt regulations regarding the criteria and procedures for authorisation and permission in this regard

[10] The Thai Act provides for the examination of the application as to substance. If it appears that the application for registration does not comply with the rules and procedures or that the claimed formula is not registrable (e.g. the formula is a national formula or has been registered as a personal formula by another person), the registrar may reject the application

medicines by traditional healers, and (iii) production of drugs for household use or for use in State hospitals.

3.2.1.2 Duration of the protection.

The term of protection under the Thai Traditional Medicinal Knowledge Act was adopted in line with the copyright duration. It remains to be seen whether such a long period of protection will create an unnecessary burden on society or provide unreasonably large profits for the TK owners. The IP right on traditional Thai medicine shall be valid for a life time of the right holder of the registration and extend for another 50 years after his decease. (Section 33) In the case of joint ownership, the right extends for 50 years from the date won which the last joint owner deceased (Section 34).

3.2.1.3 Criticism

There is no express provision for benefit sharing mechanism and accessing of TK similarly the act lacking the provisions to tackle the situations like , where any one is granted IP right without taken into account of the novelty and inventiveness of the particular invention. Further it is silent about the concept like 'Prior informed consent' and 'mutually agreed terms' etc.

However it is to be noted that in the Thai law there is recognition of personal invention by an individual /tribe. .In other words, even an individual(improver or inventor) can also approach and get the status of traditional knowledge holder, rather than going under the identity of the community.

Registration is granted on a first-to-file basis, as under the patent law. One could question whether it is appropriate to apply a first-to-file system in case of traditional medicine.

3.2.2 *Philippines model:-*

In the Philippines, there are no existing intellectual property rights (IPR) on TK. No IPR recognition is given to the more informal, communal system of innovation by farmers and indigenous communities, a process that takes a long period of time. There are only measures on how to protect TK from use[11]. However it is to be mentioned that Philippines was the first country to introduce bio prospecting regulation, and set a trend for such kinds of national system to be developed .

3.2.2.1 Indigenous People's Rights Act of 1997

Regarding the recognition of community rights, Republic Act 8371 or the "Indigenous People's Rights Act of 1997" or Republic Act 8371, in general, was enacted to protect, and promote the rights of indigenous cultural communities and indigenous peoples "to control, develop, and protect their sciences, technologies, and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines, and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the

[11] http://www.unctad.org/trade_env/test1/meetings/delhi/Countriestext/Philipinestext.doc

properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts".[12]

- *Community intellectual rights:* ICCs/IPs have the right to practice and revitalize their own cultural traditions and customs. The State shall protect and develop past, present and future manifestations of their cultures, as well as the right to the restitution of cultural, intellectual, religious and spiritual property taken without their free and prior informed consent or in violation of their laws and traditions.
- *Right to indigenous knowledge systems and practices:* ICCs/IPs are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual rights. They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources and seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of fauna and flora, oral traditions, literature, designs and visual performing arts.
- *Access to biological and genetic resources:* Access to biological and genetic resources and to indigenous knowledge related to the conservation, utilization and enhancement of these resources, shall be allowed within the ancestral lands and domains of the ICCs/IPs only with free and prior informed consent of such communities, obtained in accordance with their customary laws. *PIC:* Access to indigenous knowledge related to biological resources, within

[12] Section 32 and 34 of the Indigenous and People's Rights Act or RA 8371.

ancestral lands and domains is subject to PIC of ICCs/IPs (Section 35)[13]. Disclosing the intent and scope of the activity in the language and process which is understandable to the society is a worth mentioning part of this legislation.

3.2.2.2 The Traditional and Alternatives Medicine Act (TAMA) of 1997

Another important piece of legislation, entitled *"the Traditional and Alternatives Medicine Act (TAMA) of 1997 or Republic Act 8423,"* institutionalizes the ownership by indigenous societies of their knowledge of traditional medicines. According to this law, when such knowledge is used by outsiders, the indigenous societies required the permitted users to acknowledge its source and demand a share of financial return that may come from its authorized commercial use[14]

3.2.2.3 Executive order of 247

This executive order stipulates that any access to traditional medicine should be on the basis of benefit sharing mechanism.

3.1.2.4 Criticism

Together, the two Acts and the Executive Order seem to aim at a two-tier approach of (i) promoting the use and development of traditional medicine by improving their quality and status and (ii) preventing misappropriation of traditional biological resources and medicinal knowledge by regulating access, requiring benefit sharing and establishing communities rights over their resources and knowledge.

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[13] PIC is defined as "the consensus of all members of the ICCs/IPs to be determined in accordance with their respective customary laws and practices, free from any external manipulation, interference coercion, and obtained after fully disclosing the intent and scope of the activity, in a language and process understandable to the community." (Section 3(g))

[14] Section 2 of the Traditional and Alternative Medicine Act or RA8423.

However, it is unfortunate to note that these laws have failed to provide and/or establish a system by which TK can be registered as a form of intellectual property. Community ownership of TK has not yet been operationalzed into feasible and workable implementing mechanisms. In essence, only the legal measures protecting TK from use, i.e., regulations on access to biological and genetic resources and the policy of "prior informed consent," have been enforced and observed. There is no express provision for defensive protection. And dispute arising out of the commercialization of the TK left open to the customary way of dispute resolution.

3.2.3 ***Chinese model:-***

Traditional knowledge system in china is regulated by two legislations such as Patent Law of the People's Republic of China of 2000 and Regulations on the Protection of Varieties of Chinese Traditional Medicine. The main object of the former is to promote, accelerate the inventors and the later is to improve product quality, and to ensure that the low quality medicines are not to be sold. The act is giving protection to a sectoral TK only i.e., it is limited to traditional medicine and exclusive right is guaranteed to the inventor. Scope of the patentable object is considerably large in Chinese patent law 2000[15]

[15] . *Patent Law of 2000:* product, method, and use of medicines; Product: a new pharmaceutical composition and preparation thereof, effective ingredient extracted/separated from traditional medicine, effective parts and preparation thereof, new preparation of changing the administration route, etc.;
- Method: preparation method of the products mentioned above, new or improved technology of production, etc.; Use: new indication of medicine, first medical use, the second use of the known medicine, etc.

3.2.3.1. Regulations on the Protection of Varieties of Chinese Traditional Medicine

This scope limited to medicines produced only in China and without patent protection; Limited to medicines categorized within the officially recognized classes. In the patent law 2000 protection is awarded after examining all the three criteria in the IPR law. Protection is with regard to product, method, and a new use. This act is silent about how to access TK. Though there is no requirement of novelty for getting protection under this act, yet it should pass a quality inspection. Right guaranteed under the Act is produce the protected species and exclusive manufacturing with the prior permission of health department. As a measure of defensive protection china has already developed a Chinese Traditional medicine Database.

3.2.3.2 Criticism:-

The unfortunate part of the Act is that manufacturing enterprises are considered as the right holders under this Act. This act does not recognizing the ownership of traditional communities over their traditional medicinal knowledge .

Unlike Thai model, this law does not recognize the rights of an individual owner.

One should doubt the feasibility of renewal of the right. The duration of the protection is 7 to 30 years and it can be renewed also. If one read these two provisions together it will affect the whole indigenous community adversely.

Apart from that law is silent about the benefit sharing mechanism and the concept like prior informed consent.

But on the other hand Chinese model incorporated the principle of "petty patents" for the protection of TK.

3.2.3.3 Petty patents

"Pretty patents" whether the would suit our condition in India The term `petty patents', are incremental improvements, which may fall short of the definition of inventiveness under TRIPS, but are nevertheless novel and useful. The term `utility model' was used synonymously with `petty patents', as in many cases such innovations belonged to the mechanical and designs field. The term `utility innovations' is perhaps more appropriate to describe `petty patents'. Such patents are at present granted in some 20 countries with some of them such as Australia, Malaysia and Thailand using them effectively.

In petty patent non obviousness element is not as rigid as in the patent system. The main advantage of this system is that it will accommodate a large area of traditional people's innovations. It is easier to secure and of less formalities. But on the dark part of it, its mainly granted to products only. with regard to innovations mainly granted to the mechanical part of the innovation. Recently Australia has withdrawn the petty patent provision from its law. This also generating a doubt about its effectiveness.

3.2.4. ***Costa Rican model***

Biodiversity law of the Costa Rica has taken a broader approach.[16] It developed a comprehensive regulatory framework to regulate access and benefit

[16] To regulate access and in so doing make possible the equitable distribution of the environmental, economic and social benefits to all sectors of society, paying special attention to local communities and indigenous peoples. Art.10(1),
- to recognize and provide compensation for the knowledge, practices and innovations of indigenous peoples and local communities in the conservation and sustainable use ecological of the components of biodiversity. . Art 10(6),

sharing, while at the same time addressing the relationship between access & benefit sharing, IPR and the protection of traditional knowledge. It included all these issues in the one legislation i.e. Biodiversity law of the Costa Rica No7788.

In Costa Rica, it was decided to include the protection of traditional knowledge and the practices, innovations and knowledge of indigenous and local communities within the scope of the access legislation. wild resources; cultivated or domesticated resources ; marine resources; terrestrial resources; ex-situ resources; in-situ resources; intangible components, such as indigenous and local communities' knowledge, innovations and practices; chemical and biochemical resources will come under the ambit of this legislation. The law includes TK as an intangible component within the term biodiversity.[17] And giving exclusive right to the communities such as sui generis community intellectual rights[18]this right exists and is legally recognized by the mere existence of the cultural practice of or knowledge related to genetic resources and biochemicals. Though there is provision for accees of TK by third parties, but law have given the law recognizes the right to local communities and indigenous peoples to oppose access to their resources and associated knowledge[19]. Moreover person should comply with the access policies proposed by the National Commission on the Management of Biodiversity for access and for the protection of intellectual rights concerning biodiversity. [20]

At the national, regional and international level, the concrete terms of benefit sharing are probably the most contentious issue. Some of the options are:

- to recognize the rights deriving from the contribution of scientific knowledge to the conservation and sustainable ecological use of the components of biodiversity. Art 10(7)

[17] Article 30 of the act

[18] Article 82

[19] Article 66

[20] Article 62

upfront payments; royalties; fees for materials and services; involvement of local researchers and communities in collection and in R&D; the use of local academic research institutions and universities; milestone payments. Further possibilities include training of local researchers and students, technology transfer to local institutions, licenses to manufacture and market commercial products, provision of commercial drugs at cost price, assistance with development programs e.g. in the area of health or education or legal assistance, joint ventures in activities of local interest, translation of information and reports, etc. While not specifically mentioned in the law, all of these possibilities have arisen and have been used in Costa Rica

There is no requirement like prior declaration, or official registration for granting of the *sui generis* community intellectual right. It "exists and is legally recognized by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals[21]

An inventory will be made of specific sui generis community intellectual rights that communities ask to be protected. Recognizing rights through these registers are completely free of cost and discretionary. These kinds of registration will be done at the demand of the interested parties. There is no formality attached with[22]. It is important to establish legal certainty and to ensure transparency. To achieve this, a public register has been created, but if so, a balance should be found between openness and the right to confidentiality; usually, confidentiality is one of the companies' most important demands in negotiations. So, A register of rights of

[21] Article 82
[22] Article .84

access, including to TK, will be organized by the Technical Office of the Commission.[23] But for accessing the TK you should get the prior approval of the community where the access will taken place and subsequently that should be approved by the officer of the technical office.

3.2.4.1 Criticism

This law is not a sectoral legislation. It mainly concentrates upon biodiversity. In this law protection of traditional medicinal knowledge is not dealt in detail.

As we have seen several national attempts towards the protection of traditional knowledge. It is to be noted that some of them even have a sui generis model specifically design for the protection of traditional medicinal knowledge. China and Thailand are some of the examples. Each of the countries legislations has its own merit and demerit. But since these are the working models, we can take provisons from these models and apply in India situation with mutis mudandis.

When we suggest a model for India the following elements can be considered, such as compensatory liability applied in Costa Rica; petty patent application of China; recognition of customary law as seen in the Philippines; access benefit sharing mechanism and prior informed consent introduced by the Philippines, recognition of the individual invention as introduced by the Thailand and so on.

On the other hand we can learn lesson from the dark side of these legislations by analyzing its provisions. For instance, in Philippines there is no defensive protection and IPR protection for the traditional medicinal knowledge. Similarly in China the

[23] Article 67 & 7.1

manufacturing enterprises are considered as the right holders under the Act. And it does not recognizing the ownership of traditional communities over their traditional medicinal knowledge.

Apart form these working models even the international organizations also proposed certain abstract models for the protection of traditional medicinal knowledge. for the better understanding of this topic analyzing those models also required.

CHAPTER IV

ABSTRACT MODELS PROPOSED BY THE INTERNATIONAL ORGANIZATION

&
NATIONAL ATTEMPTS

4.1MODELS PROPOSED BY THE INTERNATIONAL ORGANIZATIONS

4.1.1. *WIPO Model:-*

WIPO is a specialized organ of the United Nations[24]. It has considered the role of intellectual property systems in the preservation, protection and equitable use of traditional knowledge. In the intellectual property context, WIPO provides that 'traditional knowledge is analyzed into defensive and positive protection.[25] WIPO opined that no single definition[26] would suffice the term traditional knowledge as it includes diverse forms of knowledge of different communities. So the lack of a suitable definition is not a sufficient argument for lack of protection. In short rather than going to define the term TK, it will be advisable to find out the critical areas of TK where the protection is needed.[27]

WIPO's work on TK and folklore began in 1978, when WIPO developed a sui generis model for national protection of folklore jointly with UNESCO. In 1998

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[24] Before its establishment there are many organizations established under certain individual organization s like the assembly of Paris union, executive committee and international bureau of berne convention. The convention establishing the WIPO was signed at Stockholm on July 14 1967. The head quarters of the WIPO is in Geneva.

[25] We already discussed in the 2nd chapter. for more details see section 2.2.1

[26] WIPO defined TK as Traditional knowledge includes all fields whether they be artworks, handicrafts, folklore, environmental preservation, medicinal plants, products and processes in medical treatments and whatever knowledge that benefits the communities. The knowledge is transferred through individuals, families or groups of people in the community.

[27] World Intellectual Property Organization (WIPO), *Intellectual Property and Traditional Knowledge* (WIPO Publication No. 920 (E), Booklet No.2) 4.

WIPO launched a new work program, including, inter alia, fact-finding missions to 28 countries on intellectual property and TK, which produced a global report on 'Intellectual Property Needs and Expectations of TK Holders' and three case studies on the role of IP rights in the sharing of benefits arising from the use of biological resources. The main objective of these activities was to identify and explore the intellectual property needs and expectation of the holders of the traditional knowledge holders.

4.1.2 ***An overview of WIPO model provisions***

4.1.2.1 Scope of the subject matter[28]:

Keeping in the evolving nature of traditional WIPO tries to inculcate all the components of traditional knowledge which comes from the intellectual activity created, transmitted and through generations. It includes know how, skills, innovations, practices, knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge. WIPO added this enivormental component under the consent request of some countries.

4.1.2.2 Benefit sharing mechanism and recognition of knowledge holders[29]

If the Commercial or industrial use has a gainful intent and confers a technological or commercial advantage then it should be subject to just

[28] Article 3
[29] Article 6

and appropriate compensation for the benefit of the TK holder, and such compensation would be based on with fairness and equity principle.. Compensation should be in a form that responds to the express needs of the TK holders and is culturally appropriate holders.

4.1.2.3 Concept of prior informed consent

The model law emphasized that any direct access or acquisition of TK from its traditional holders, should requires prior informed consent[30] from the holders of the TK. Principles of prior informed consent and relevant national laws will regulate the access in to it. The holder of TK shall be entitled to either grant prior informed consent for access to TK, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation.

According WIPO duration of the protection[31] will be depends upon 3 variables

- As long as the TK fulfills the criteria of protection
- As long as it maintained by the TK holders
- The period which it remained as the collective identity of the community.

4.1.2.4 Protection against misappropriation

WIPO lays down what are the Specific acts of misappropriation. Acquisition of TK by theft, bribery, coercion, breach of contract,

[30] Article 7
[31] Article 9

misrepresentation, etc are considered as misappropriation. Apart from these direct misappropriations, Acquisition of TK in violation of prior informed consent, Commercial use of TK without equitable compensation or benefit benefit-Sharing and Other acts of unfair competition can also come under the term misrepresentation.

In the interests of transparency, certainty and the conservation of TK, relevant national authorities may maintain registers or other records of traditional knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of TK holders. Such registers may be associated with specific forms of protection, and should not compromise the status of hitherto undisclosed TK or the interests of TK holders in relation to undisclosed elements of their knowledge.

WIPO suggested that Legal and administrative mechanisms should be established to provide effective protection in national systems for the traditional knowledge of foreign rights holders. Measures should be established to facilitate as far as possible the acquisition, management and enforcement of such protection for the benefit of traditional knowledge holders in foreign countries.

4.1.2.5 Criticism

After the analysis of key provisions of the WIPO model one can come to a conclusion that WIPO provisions are not new it just cherry picked

provisions from the existing frame works and the experiences. Further more it does not address any legal form, it lays down the substance of the protection. It attempts to prevent misappropriation and providing protection for TK holder and even provider countries of the TK . It allows the wide range of legal approaches which are currently being used to protect TK in various jurisdictions. It leaves national authorities a maximum amount of flexibility in order to determine the appropriate legal mechanisms which best reflect the specific needs of local and indigenous communities in the domestic context and which match the national legal systems in which protection will operate.

4.1.3 *OAU model*

The Organisation of African Unity has drafted an " African Model Legislation for the Protection of the Rights of Local Communities, farmers and Breeders, and for the Regulation of Access to Biological Resources". The preamble of the model legislation declares that "the State recognizes the necessity of providing adequate mechanisms which guarantee a just, equitable and effective participation of its citizens in the protection of their collective and individual rights and in making decisions which affect the biological, genetic and intellectual resources as well as the activities and benefits derived from their utilization." It seems to incorporate the most comprehensive and novel set of objectives for the protection of traditional knowledge and the biological resources on which they are based. The main aim of legislation is

to ensure conservation, evaluation and sustainable use of biological resources and knowledge and technologies in order to maintain their diversity.

The model legislation specific objectives can be summarized as follows:

Recognize, protect and support the inalienable rights of local communities including farming communities and the rights of breeders over their knowledge and technologies; Promote fair and equitable sharing of benefits arising from the use of knowledge and technologies; Provide an appropriate for access to community knowledge and technologies and a mechanisms for the implementation and enforcement of rights of local communities and conditions of access to biological resources, community knowledge and technologies. Ensure effective participation of concerned communities in decision making and thereby encourage national and grassroots scientific and technological capacity

For the better fulfillment of above mentioned objectives, law stipulates that any written contract shall be entered into by the state and the collector that should be with the full participation and approval of the concerned local community or communities. This OAU model also respects and recognizes customary of law of the communities, wherein which it suggests to the nations an institutional arrangement for developing a system of registration of items protected by community intellectual rights and farmers' rights according to their customary practices and law. It further suggested that there should be national information system which compile and document information on local knowledge and innovation practices of the communities and guidelines for collectors of resources. This law recognizes the

community right (intellectual right) that the customary practices of local communities derive from a priori duties and responsibilities to past and future generations of both human and other species. This law gave greater importance to the, recognition and protection of the multi-cultural nature of the human species. This model emphasized that the concepts of individual ownership and property arose community rights are regarded as natural, inalienable, pre-existing or primary rights. Therefore they have the right over biodiversity. This proposed system of rights, which enhances the conservation and sustainable use of biological diversity and promotes the use and further development of knowledge and technologies, is absolutely essential for the identity of local communities and for the continuation of their irreplaceable role in the conservation and sustainable use of this biodiversity.[32]

Access to biological resources or knowledge is subject to prior informed consent of the communities. They have the right to put restriction or even withdraw the consent. One should respect their customary laws and rules.

4.2 PROTECTION AT NATIONAL LEVEL

4.2.1 Ancient Indian thought

In ancient it is believed that knowledge should follow freely. It is the duty of each disciple to transmit his knowledge acquired from his *Guru* (teacher) to world. That was considered as the *guru dhakshina/ rishi rina (*obligation towards his teacher). So in ancient India knowledge is not a property of a private person anyone can acquire, whoever wishes to. But in the medieval period we could see even in India king used to give certain amount of money as gift or as matter of respect to those persons who come up with new useful

[32] Supra n, suman sahai

inventions / knowledge to his kingdom. But these rewards generally limited to either certain amount of money or some position in king's court.

4.2.2 ***Constitutional protection of Traditional medicine knowledge:***

There is no express provision in the constitution for the protection of traditional knowledge. However, article 29 talks about minority rights. It guarantees the right of the minorities to conserve their culture and script. Similarly even in article 51 A(f), conferring duty on all citizens of India to protect and preserve the rich heritage of our composite culture. Even the recognition of customary laws of the tribal communities can be seen in Article 371 A.

In India there is no comprehensive system of protection of TK has been devised, but there have been a quite number of legal initiatives on the part of India to protect its vast variety of biodiversity and TK associated with it. Ruthless Exploitation of biodiversity and the TK by the transnational corporations made realize the inadequacy of the Legislations. Therefore amendments were made in the Patents Act, 1970, in the year 1999 and more recently in the year 2002. Also the Biological Diversity Act, 2002 has been brought into effect. These acts of the Legislature were made to uphold the spirit of the Convention on Biological Diversity which provides a comprehensive and internationally binding legal framework for the protection of biodiversity and for the recognition of sovereign rights of

the Third World over biodiversity and its components. But unfortunately these acts promote corporate hijack of biodiversity and knowledge.

4.2.3 ***Indian Patent act*** **:**

The Indian patent has been amended several times to meet the timely requirements; the latest amendment was on 2005. But unfortunately Indian patent act is not dealing the issue of traditional knowledge that elaborately in the act despite of the fact that India is having a high level traditional medicinal knowledge in its credit. But it does not mean that there is no specification TK in the Indian patent act. Section 3[33] stipulates that traditional knowledge is not an invention, there by no one can acquire patent upon it. It further clarify by section 24A no grant of exclusive right to sell or distribute any article or substance based on the system of medicine or substance that is already in the public domain. Further the patents (amendment) Act, also contain provisions for mandatory disclosure of geographical origin and source of the biological materials used in the invention at the time when the patent is being applied for.[34] Further to safeguard against non disclosure and wrongful disclosure, provisions have been incorporated to include the non disclosure or wrongful disclosure as grounds for opposition and revocation of the patent, if cases where the same has already been granted[35]. It is interesting to point out here that the patent might at times be based on such

[33] Section 3(p) an invention which in effect is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.
[34] Section 10 (4) (ii) (D),patents amendment Act,2002
[35] Section 25(j)&(k),patent amendment Act 2002.

knowledge, which might not always be documented. Keeping this in mind provisions have been incorporated to include anticipation of invention by available local knowledge, including oral, as one of the grounds for opposition as also for revocation of patent, if the same has already been granted.[36]

4.2.3.1 Criticism

Though there are provisions which are prohibiting the patenting of TK. But there is no express provision which confers right to the local communities who are holding the TK. Another lacuna is there is no provision as to how to access the TK and whether the local communities can seek for benefits if any one commercially exploits. One should admit that defining TK is a difficult task and there are chances it may adversely affect the communities interest also. Yet it will be advisable to give a definition which is inclusive in nature.

4.2.4 *The Biological Diversity Act, 2002*

The biodiversity act passed by the parliament of india in December 2002, was to implement India's obligation under convention on biodiversity conservation of the UN. The main aims of the act are as follows:

- The need to conserve biodiversity
- Recognition of community rights and indigenous culture and knowledge

[36] The patent amendment Act 2002.

- The potential to prevent biopiracy. i.e., the theft and patenting of indigenous knowledge related to biodiversity.

As per the provisions contained in the Act the national, state and local biodiversity boards /committees are entrusted to oversee and implement benefit sharing mechanisms, documentation of bio resources and traditional knowledge, material transfers, access agreements on genetic resources and technologies and so on. The act stipulates norms for access to biological resources and traditional knowledge based on three ways

- Access to biological resources and traditional knowledge to foreign citizens, companies, and NRI based on prior approval of NBA. [37]
- Access to Indian citizens, companies, associations and other organizations registered in India on the basis on the basis of prior information to the state biodiversity board [38]
- Exemption of prior approval or intimation for local people and communities, including growers and cultivators of biodiversity and vaids and hakims who have been practicing indegeouns medicine[39]

Chapter II of the act deals with the regulation of access to biological diversity section 4 stipulates person should take prior approval from the NBA, for transferring the result of any research relating to biological resources obtained in India. Further it says, previous approval of the NBA is mandatory for applying

[37] Section 3 of the Act
[38] Section 7 of the act
[39] Ibid

intellectual property right in or outside India for an invention which is based on the research or information obtained from India.[40]

Benefit sharing mechanism

The act subject to section 21 and rule 20 of the biodiversity rules, insists up on inclusion of appropriate benefit sharing provisions in the access sharing agreement on mutually agreed terms related to commercial exploitation [41] while deciding benefit sharing agreement NBA can include all or any of the manner described in section 21 (2), which includes granting of joint ownership over IP right, transferring of technology, conduct the research and production in such area , participation of benefit claimers, setting up of venture capital fund or payment of monetary compensation. The time frame and the quantum of benefit to be shared will be decided by the NBA on case to case basis. If the holders of the knowledge is not able to identify then the benefit will goes to the NBA fund.

4.2.4.1 Criticism

Earlier draft of the bill had four parts. However the draft passed by the parliament has no conservation element, no recognition of the community right to biodiversity no regulation of adverse impact.[42] . It is clear that pressures were put on the ministry to drop clauses on regulating adverse impact in earlier drafts. The

[40] Article 6(1)

[41] Article 21(1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

[42] Shiva vandana etl ;corporate hijack of biodiversity ;first Edn; Navadanya; New Delhi;p 34

act is reduced to an act to facilitate and legalizes the biopiracy instead of preventing it[43]. This act has failed to recognize the legal standing of local communities and their inalienable rights to their biodiversity and collective innovation in spite of the constitutional framework. If one analyze the provision it is dismal to note that there is no provision for the respect of customary practices, and similarly participation of the indigenous communities are not that appreciated in this legislation. Further more, NBA has vested with the ample powers, which may adversely affect the interest of the community, if NBA turned in to corruption. In short this act miserably fails to do what it was designed to do — stop Biopiracy and recognition of communities' right.

4.2.5 *The protection Plant varieties and farmers' right protection (PPVFR) Act, 2001*

The PPVFR act 2001 deals primarily with the protection of plant breeder's right over the new varieties developed by them. This act recognizes the rights of the local and village communities, who have contributed to the evolution of variety and entitled to compensation. A unique aspect of this act is that it confers three concurrent rights to breeders , to farmers, and to researchers. Not only does the 2001 Act protect the rights of farmers to save, use, exchange and sell farm-saved seed, it also seeks to ensure that these seeds are of good quality, or at least that farmers are adequately informed about the quality of seed they buy. In addition, safeguards are provided against innocent infringement by farmers. Farmers who unknowingly violate the rights of a breeder are not to be punished if they can prove that they were not aware of the existence of such a breeder's right (Art 42).under this act any farmer or group

[43] Ibid

of farmers or community of farmers claiming to be a breeder of the variety can apply for registration of their varieties.

4.2.5.1 Criticism

The real emphasis is on protection to the breeder, means most of the time protection which only facilitate the private seed developer. And farmers are prohibited to sell these protected varieties of the "branded" varieties of the seed. So it jeopardizes the interest of the farmers and our agriculture. Though this is a sui generis law for the protection of the plant varieties but there is little provision relating to the protection of traditional medicinal knowledge.

4.2.6 ***Other laws***

The drugs and cosmetics Act 1940, manufacturer or seller of a drug has to inform where he has got the drug. Government already mentioned what are the authoritative texts for plasticizing ayurveda. This is same in the case of Unani also. Form the field work researcher able to find out that not only this Act, but there are some other acts that also affecting the traditional medicinal knowledge, not directly, but indirectly.

Some of those acts are Indian forest Act 1972, which regulates the use of forest and forest produce. Those who want to exploit the forest produce required to get license from Government of India. Local communities can use the forest products. But it is to be noted that, even among the commercial exploiters of ayurveda like AVS, kottakal express their concern that they are finding difficulties in getting plants and plant parts which are needed for the formulation of traditional medicines. One of the reason that expressed, widespread acceptance of traditional medicines stimulates the growth of numerous commercial

exploiters of traditional medicines, which ultimately leads to the over exploitation of forest products.

So researcher has of the view that a sui generis model should address this element also. Preservation of traditional medicinal knowledge will be complete unless and until we protect its components of that particular traditional medicinal knowledge.

CHAPTER V

KERALA INTELLECTUAL PROPERTY POLICY 2008

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FIELD STUDY

Kerala is one of the smallest states in the Indian union. Its area is 38.855 square kilometers which is just 1.3 percent of the total area of India. Its unique geographical position and peculiar physical features have invested Kerala with a distinct individuality. Hence it has played a vital role in the commercial and cultural history of India. Though area wise Kerala is small, but its veritable variety of herbs and traditional knowledge has made this state a frontrunner in traditional medicinal knowledge.

In Kerala there are still 37 Scheduled Tribes out of 48 tribal communities; their number is only 1.14% of the state's population[1]. There were only five primitive tribe[2] in Kerala and most of these tribes are forest-dwellers and food-gatherers. Increasingly, they are found living on the fringes of the forests near the highways and the villages of the plainspeople, yet apart from them. They are completely depending up on the forest and forest products. Since Kerala become the hub of various herbs, the traditional knowledge attached with it cannot be ignored. It has a well developed traditional knowledge with regard to health care system which equally stands with or more than the

[1] http://www.scheduledtribekerala.gov.in/population.htm

[2] Tribal groups with pre-agricultural stage of development, diminishing/dwindling population and very low literacy rates are defined as Primitive Tribe Groups (PTGs).Cholanaikans, Kurumbas, Kattunaikans, Kadars and Koragas are the 5 primitive tribe groups in Kerala. They constitute nearly 5 % of the total tribals in the State. Kattunaikans are mainly seen in Wayanad district. Their other areas of habitation are Malappuram and Kozhikode districts. Cholanaikans are said to be a sub-community *of* the Kattunaikans and are seen only in Malappuram District.Nearly 59 % of the Kadar population is found in Trissoor district and the balance in Palakkad district. Kurumbas are living in the Attappady Block of Palakkad district. The Koraga habitations are in the plain areas of Kasaragod district. Available at http://www.scheduledtribekerala.gov.in/population.htm

western medicinal knowledge in compared to its efficiency. The experience of the "turmeric patent case" and "jeevani case" made realize the Kerala society the importance of the protection of their traditional knowledge.

5.1. BACKGROUND OF THE POLICY

The major issue being addressed by the Kerala IPR Policy 2008 is with regard to protection of traditional medicinal knowledge and biodiversity. The main reasons to take these issues into account, as expressed in the policy, can be summarized as follows.

- Traditional Knowledge is not sufficiently codified;
- There is no formal mode of transmission of TK;
- TK is not coming in the ambit of any legally defined Intellectual Property Rights.
- This kind of knowledge attributes to and forms the basis of livelihoods of many TK practitioners.
- Absence of legal property rights on such knowledge which stimulates the misappropriation of the knowledge by the multi national entities and achieve patent right over it.

The government of Kerala constituted a core committee empowered with the task of drafting the intellectual property rights policy for the state in the year 2004[3]. But government felt that the draft IPR policy as prepared by the Core Committee required certain modification, therefore, another committee was constituted under the chairmanship of Hon. Minister for identifying the modifications and to finalize the Draft IPR policy. The committee finalized the draft policy and submitted for the approval of the government and

[3] G.O. (Rt)No.815/2004/Law, dated 4.8.2004 of the Law (Nodal) Department.

the same come into force on 3.6.2006[4]. Kerala thus became the first state to come out with a policy on intellectual property rights.

5.2. SALIENT FEATURES OF THE POLICY

There are three basic practical issues that the IPR policy addresses. The *first, and by far the most important,* relates to the protection of "traditional knowledge", especially Ayurveda. The "traditional" nature of "traditional knowledge" is expressed not just in its being insufficiently codified, or in the non-formality of its mode of transmission, or in its not being subject to any legally-defined property rights; it is expressed also in the fact that it remains largely outside the domain of capitalist, especially corporate, operations. While it yields livelihoods to many, or forms the basis for practice for many, the absence of legal property rights over such knowledge creates scope for its private misappropriation. The IPR policy suggests a legal arrangement for preventing this.

Such knowledge obviously cannot be transformed into private property of any sort. At the same time it cannot simply be put in the public domain, since, this, while preventing *direct* private patenting of existing knowledge and practices, would not prevent their *indirect* private appropriation, through what will be claimed as "improvements" but constitute mere repackaging or minor modifications[5]. The Kerala government's approach therefore is to put all such knowledge and practices in the domain of "knowledge commons" which have two main characteristics: first while such knowledge is available for non-commercial use by anybody, its commercial use can be made only through negotiations with the existing right-holder; and secondly, any improvement made on the basis of this knowledge will have to be put back into the "commons". More precisely, the proposal is as follows.

[4] Kerala intellectual property policy 2008.
[5] http://pd.cpim.org/2008/0706_pd/07062008_10.htm viewed on May 31st, 2008, Time: 20:10 PM;

Within the corpus of traditional knowledge, it distinguishes between two components. One refers to knowledge which is the preserve of particular communities, especially tribal communities, or particular institutions, or particular families, often located in specific regions, and passed down from one generation to the next in a variety of traditional ways. The other refers to knowledge whose practice sustains the livelihoods of many persons scattered across the state, *which does not have any specific community or family custodian.* Thus while Kotakkal Ayurvedic massage clearly belongs to the first category, the knowledge that sustains the daily practice of Ayurvedic medicine by numerous practitioners strewn across the state belongs to the second.

5.2.1. "*Knowledge of commons*":-

According to this policy the State proposes that all traditional knowledge, including traditional medicines, the practice of which sustains livelihoods of many, should come under the realm of "Knowledge Commons" and not to the "Public Domain". Later it defined the "Knowledge Commons" which refers "the knowledge, which is the collectively produced sphere of ideas and which is left unencumbered for the greater benefit of all". Further this policy stipulates creating property rights on all traditional knowledge holders. They will be deemed to be holding their rights under an obligation that they shall permit others the use of the knowledge in their possession for non-commercial purposes.

5.2.2. *Types of traditional knowledge:-*

In the legal arrangement proposed by the Policy, Traditional Knowledge is categorized into two. In the first category, Traditional Knowledge refers to such

knowledge preserved and passed from one generation to the next generation, in a variety of traditional ways, by particular communities (especially tribal communities), particular institutions or families regionally located[6]. The second category pertains to the Traditional Knowledge that sustains the daily practice of Ayurvedic medicine by numerous practitioners scattered across Kerala In respect of the first category of TK, where it is the preserve of a particular community, particular institution or family, such community or custodian will be deemed as the right-holders of TK. These right holders will have two kinds of rights

- Right for a "brand name" or a name associated with the unique practice of such community, family or institution, say "Kottakkal Massage" for Example.
- Right to use the Knowledge for Commercial as well as Non-commercial purposes.

Anyone other than the right-holder to the traditional knowledge, who wishes to use this knowledge, may do so under a "Common License". **If any commercial use of the traditional knowledge is to be made by any entity other than the right holder, the terms and conditions for such license will have to be negotiated between the right-holder and the said potential user.** Any use of traditional knowledge or practice in violation of the "commons license" within or outside the state of Kerala will be considered a violation of the rights. No entity that is registered as a medium or large enterprise would

[6] Kerala intellectual property policy 2008

ever be acknowledged as a right holder. It is further stipulated that any development made using this knowledge licensed under the above obligation should be put back to the realm of "Knowledge Commons", say "Traditional Knowledge Commons", and hence denying the scope of patenting thereof.

In respect of the second category of TK, there is a livelihood of numerous practitioners strewn across Kerala; State will be deemed to have rights over such Traditional Knowledge. Here, even though State holds the ownership on such TK, all the actual practitioners of this Traditional Knowledge will have an autonomous license for right of commercial use from the State, provided that such practitioners are not classifiable as medium or large enterprises. But these Licensees are not empowered to sub-license this right of commercial use to anybody else, and right for transferring licenses will solely be enjoyed by the State, i.e. the right holder.

Any use of traditional knowledge or practice in violation of the "commons license" within or outside the state of Kerala will be considered a violation of the rights of the right-holders and will invite prosecution.

5.2.3 *Authorities under the policy*

5.2.3.1 Supervisory Council on Intellectual Property (SCIP)

The Policy proposes to set up a specialized governmental body called the Supervisory Council on Intellectual Property (SCIP) to oversee the activities of the KTKA and SBB with regard to the protection of traditional knowledge, to provide overall supervision in matters relating to intellectual property rights, and to follow up

the recommendations of the KTKA with regard to prosecutions for violation of knowledge-users' rights.

5.2.3.2 Constitution of SCIP.

Chief Minister will be its Chairman and Law Minister will be the Vice-Chairman

The Chairpersons of the SBB and of the KTKA will be ex officio members.

Its Members shall include a few ministers, Scientists and other experts from various fields

The Council will have appropriate technical staff

The Council will operate through a number of sub-committees and specialized groups, which will meet frequently and deal with specific issues.

5.2.3.3 Major Functions of SCIP

- It will pursue all cases of breach of agreement on knowledge-user's right.
- It will be the conduit through which all the patent applications from state government-funded or state government-aided research institutions will pass.
- It will help any potential patent applicant who asks for its assistance to prepare proper patent applications.
- It will assist all those who are on the verge of patentable inventions but are held up in their research work and cannot complete it for some reasons (including financial constraints).
- It will encourage in various ways patentable research in the state.
- It will disseminate knowledge in the state about intellectual property rights.

- It will in general uphold and promote the interest of the state and its people in whatever way it deems fit in the new International IPR Regime.

5.2.4 *Kerala traditional knowledge authority*

Creation of rights and obligations necessitates a Governing Mechanism for acknowledging the right holders, enforcing the rights and recommending legal action against the violators of the rights and "Common License". Therefore the Policy advises to constitute a body called Kerala Traditional Knowledge Authority (KTKA), with which all practitioners of traditional knowledge of the first category will have to be registered. The Board shall consist of a Chairman and four members, of whom at least one each must be from the TK community and the scientific community Such practitioners will have to specify what is unique about their actual traditional-knowledge-practice, the details of the nature of their practice, and the details of the nature of the community/group/individual that constitutes the custodian of this practice. KTKA will give general notice to the public, regarding all applications being made to it by practitioners. This is to invite public for bringing to the attention of KTKA, any disputations of applicant's claims or challenges to claims of uniqueness, prevalence of similar practice in more than one location or community etc. After scrutinizing all such cases of disputes and after resolving the issue of ownership, KTKA would finally register a community/group/individual as knowledge practitioner of such unique set of TK practices.

The activities of KTKA shall be financed from a fund created by the Government of Kerala. KTKA shall maintain a register of all such TK practitioners of the first category, who have registered with this Authority. KTKA also shall have the obligation to help right holders viz. the State and the Private Communities to negotiate terms with the other possible

commercial users of traditional knowledge, and undertaking promotional activities like forming 'Traditional Knowledge Users' Co-operatives", in order to enable such users to access larger markets for their practices and products.

5.2.5 *TK associated with use of Biological resources*

A mechanism would need to be put in place against misappropriation of TK associated with the use of Biological resources by Indian Corporate. Section 7 of the Bio-diversity Act 2002 provides that "No citizen of India or a body corporate, association or organization, which is registered in India, shall obtain any biological resources for commercial utilization, or bio-survey and bio-utilization for commercial purposes, except after giving prior intimation to the State Biodiversity Board concerned". However this provision does not apply to the local people and communities of the area, including growers and cultivators of biodiversity and the practitioners of indigenous medicine. But there is a drawback that this section does not cover obtaining knowledge associated to the biological resource. Therefore it requires that the Section 7 be extended, through appropriate legislation if necessary, to make it obligatory for the applicant (all Indian citizens other than the local users) to obtain prior approval of the State Biodiversity Board for the use of knowledge associated with biological resources also. This can help to ensure that the traditional knowledge remains within the realm of "Knowledge Commons"[7].

5. 2.6 *Ownership of IPR in research*

In respect of **the projects funded by private sources or by foreign official sources**, the Policy stipulates that the knowledge generated in such research shall be put in to the domain of "commons", so that any one can use these for whatever purpose, and all useful

[7] www.google.com

modifications derived from or based on these will be put back in to "commons" available for anyone to use.

In the case of **Projects funded by State Government or from the general research funds of the institution** itself, the research outputs must clearly be the property of the state government, but a suitable system, of rewards will be introduced, by the Supervisory Council on Intellectual Property (SCIP), for the research scientists upon whose work the output is based. The State Government may decide to put the research output in many cases in the domain of "commons" but that will be its own decision, to dispose of its "intellectual property" in any manner as it deems fit.

In the case of **Projects funded by the Central Government or by other official agencies of the country**, the intellectual property rights over the outcome of research should be left open and decided on a "case by case" basis, since the research partners in these cases may well have their own rules regarding the intellectual property status of outcomes of joint research.

5.3. CRITICISM OF THE POLICY:

An analysis of the policy provisions would reveal that there are many loop holes in the policy which should be addressed for the better protection of traditional medicinal knowledge. Some of the grey areas of the policy that I found out during my research are as under:

1. If we look at the categorization of traditional knowledge under the policy, we would find that the policy does not lay down any mechanism for facilitating the negotiation between the tribes and big corporation and therefore fails to

ensure the parity of powers as neither the SCIP nor the KTKA are involved in the negotiations process. The point here is that if no clear mechanism is laid down to protect the interest of the tribes, the entities using their traditional medicinal knowledge will cheat and deny them their due. In such a scenario the basic purpose behind bringing the policy would be destroyed and the tribal interest be jeopardized.

2. Further, if we look at the spread of traditional knowledge practicenors in Kerala, we will find that it yields livelihoods to many, or forms the basis for practice for many. It is true that the absence of legal property rights over such knowledge creates scope for its private misappropriation. The 2008 Policy aims to lay down the framework to ensure that such knowledge cannot be transformed into private property of any sort. The policy also acknowledges that such knowledge cannot simply be put in the public domain, since, this, while preventing direct private patenting of existing knowledge and practices, would not prevent their indirect private appropriation, through what will be claimed as "improvements" but constitute mere repackaging or minor modifications[8]. The approach of the Kerala government's therefore is to put all such knowledge and practices in the domain of "knowledge commons" which have two main characteristics: first while such knowledge is available for non-commercial use by anybody, its commercial use can be made only through negotiations with the existing right-holder; and secondly, any improvement made on the basis of this knowledge will have to be put back into the "commons". Thus it might

[8] http://pd.cpim.org/2008/0706_pd/07062008_10.htm viewed on May 31st, 2008, Time: 20:10 PM;

appear that the policy very clearly stipulates that any minor development to a traditional medicinal knowledge shall at the most be liable to a common license and that no patent can be claimed on any such minor development. However, the ambiguity manifested in the provisions in this regard however is that even though the policy is very clearly brings any minor improvement upon traditional knowledge in the knowledge of commons, yet the policy does not specify anywhere as to who shall decide whether there is a minor development or not.

3. Further, the policy proposes to put the patents taken out on research output by the state government research institutions funded by private by private or foreign sources in to "knowledge of commons". The practicability of such is seriously doubtful.
4. Another interesting that might be noticed is that even though the policy provides for the different authorities but it fails to clearly outline their functions. To give an example here – the policy proposes to constitute a supervisory council on intellectual property to oversee the IPR governance in the state; however the policy remains silent about the deployment of working group to deal with the day to day administrative matters of SCIP.
5. Within the corpus of traditional knowledge, one of the components refers to knowledge which is the preserve of particular communities, especially tribal communities, or particular institutions, or particular families, often located in specific regions, and passed down from one generation to the next in a variety of traditional ways. It is quite understandable that traditional knowledge is a property attributable to the tribal communities or particular

families, which has been carrying their traditional medicinal knowledge from generation to generation, however one fails to understand how traditional knowledge can be attributable to an institution. Thus giving a traditional knowledge holder status for "institution" seems to be illogical. Even during the course of my fieldwork, I found that the Kotakkal ayurvedasala is practicing "pancha karma', an ayurvedic massage known as "kottakal massage". Thus while Kotakkal Ayurvedic massage at the most belong to the second category as it is the same knowledge that sustains the daily practice of Ayurvedic medicine by numerous practitioners strewn across the state. This being the case I would rather say that the policy should be amended to take institutions out of the first category.

6. It is a fact that intellectual property law falls within the union list as Entry 49 of the Constitution of India. However the same is limited to "Patents, inventions and designs, copyright, trade-marks and merchandise marks. In such a case the power of the Kerala government to bring such legislation itself becomes questionable. It is further interesting to point out that Article 248 of the Constitution, which deals with the "Residuary Power" provides that in all matters not enumerated in any of the lists, power shall vest with the union government to legislated in that regard. One cannot say that the policy is limited only to traditional knowledge and is devoid of any IPR component for even in such a situation the power to legislate on the subject matter would lie with the union government vide Article 248 itself. Such being the scenario one fails to understand the logic behind a state legislation.

5.4 FIELD WORK

Place: kottakal arya vaidya sala.

Date: 1. 5.09 & 12. 5.09.

5.4.1 *Place of felid work*

Researcher chooses Arya Vaidya Sala, Kottakal for her felid study. When we go to kottakal, we will realize the name 'town of medicines ' (marunnu nagari) is an appropriate name to call that district. Even the wind is also carrying the smell of old herbal formulations. Kottakal Arya Vaidya Sala founded in 1902, by Vaidya Rathnam P.S. Varier. Now this charitable society develops as India's rich ayvurvedic medical heritage.

5.4.2 *Identification of samples:-*

Researcher identified 20 employees from the arya vaidya sala , it includes both officers and other employees in the lower wrung.

Apart from that researcher had a face to face talk with the local people (randomly chosen) also and collected information.

5.4.3 *Methodology of data collection:-*

Researcher used interview schedule as the tool for data collection. Most of the questions are of open ended. But researcher regulated to the extent possible to focus upon the topic.

5.4.4 *Limitation of the study*

This study is limited to the academic purpose only. Whatever analysis comes out from the study is purely for academic purpose. This study is purely confine to the aspects of this topic.

5.4..5 *Interview 1:- K.V. Rama chandran, Chief Manager herbal materials*

Q1: ***Could you please explain the method of herbal collection?***

Ans: Mainly there are 3 types of herbs are being used by the Arya Vaidya Sala ie, fresh herbs, dry herbs and seasonal herbs/ or trade herbs .among these, fresh herbs and dry herbs are collected from the local Muslim herbal collectors. There are around 70 traditional Muslim families used to provide herbs to kottakal Arya Vaidya Sala since its beginning. And they are mainly from the region of Vayanad, and Palakkad. [9] Trade herbs or seasonal herbs are collected from the traders out side Kerala. Because those herbs are not available in Kerala, these are mainly seen in the valleys of Himalaya, north east regions and other parts of the India.

*Q2: **Could you please relationship between the Muslim herbal collectors and the Arya Vaidya Sala?***

Ans: As mentioned above they have been employed at the time of Vaidaratnam P.S.Varier , even today, they are continuing the practice of collecting and providing herbs to the kottakal AVS . However their employment is on the contractual basis. Every year there will be a negotiation between the Arya Vaidya Sala and one person representing the familes. In that negotiation they will decide the remuneration to the collectors. They will fix a particular sum of money to a particular species of plant in kilograms. The money will pay through check only in the name of one person among them. As of today there is no conflict between these familes and Arya Vaidya Sala and moreover they are happy in working with the Arya Vaidya

[9] Though researcher asked names of few families , but they reluctant to reveal it, as it is their matter of business policy.

Sala. AVS never looking into the issues of distribution of remuneration among the musilm families.

Q3 :Are these Muslim herbalist contributed in to your medicinal knowledge?

Ans: No, they are local herbalist only. They can identify different plants (that includes medicinal plants) but they are not *nattu vaidyas* (indigenous doctors). Moreover Arya Vaidya Sala seek help from only auyrveda book that has listed out in the Drugs and Cosmetics Act, 1940

Q4: Is there any mechanism through which Arya Vaidya Sala sharing its benefits with local tribes / people?

Q4B If yes, can you throw some light on the benefit sharing mechanism of Arya Vaidya Sala ?

Ans: Arya Vaidya Sala is a charitable institution, the benefits arised from the working of Arya Vaidya Sala is divided into following propotion as explained in the will of the founder Vaidya Ratnam P.S.varier ie, 40% of company profit is utilized for the treatment of poor patients in the companies hospital, 10 % to the educational institution, 10 % research and development and 40 % for the administration. No one can take any dividend.

Other than that Arya Vaidya Sala is a charitable institution, they don't have any specific mechanism through which ayurveda sala can share its benefits.

Q5 Do the local people participate in the herbal collection?

Ans: There is no direct participation as such from the local people. But it is to be noted that, they never hesitate to give any herb that are growing in around their house to Arya Vaidya Sala as and when it requires.

5.4.6_*Interview 2 :- Venu Gopal , interview with Chief Manger Legal*

QI What is the source of medicinal knowledge of the Arya vaida sala , is it only from 'Veda' or the Arya Vaidya Sala has taken help from other local and traditional sources ?

Our preparation are purely based upon the ancient ayurvedic texts such as vedas, sustra samhitas, charaka samhitas, ashtanga hyrdayam,etc. apart from these sources we are not taken any help from the local traditional healers.

Q2 In your opinion what are the problems faced by the traditional Indian medicinal knowledge holders?

Being a commercial exploiter of the Ayurvedic knowledge, Arya Vaidya Sala is not against the concept western medicinal knowledge. Initial there was a greater reluctance from the part of the local communities to undergo ayurvedic treatment, for that they were more influenced by the western medical system.

Q3 What is your opinion about TKDL in Kerala? Will it solve the problems of misappropriation of TK?

Forming TKDL is a good option and a substantial part of the Ayurveda knowledge already digitalized. Though TKDL may facilitate more competition among the companies, but its an alternate way to tackle the problems of misappropriations. However forming of TKDL per se would

not completely eradicate the problems of misappropriation of TK. There should be right based and systematic approach on the part of the government.

Q4 Are you aware of kerala Intellectual property policy 2008? Do you think that it will afford better protection of TK?

Yes I am aware of the Kerala IPR policy 2008. But in my opinion this is a policy which made without much homework. They did not address the issue of low literacy rate among the tribes. In my opinion there should be a greater involvement from the part of the government to help the tribes.

Q5 Would traditional IPR provide an effective protection?

Traditional IPR would not provide an effective protection. That we had witnessed in the cases of turmeric patent, Neem patent and basmati rice patent etc. so these instances itself showing the ineffectiveness of the protection of Traditional IPR system.

Q6 Would 'sui generis' model be a good alternative?

Yes sui generis protection for traditional medicinal knowledge will be a better alternative for TK protection.

Q7 Our understanding of sui generis is the models provided by the WIPO, china, and Thailand. In your opinion what changes do you suggest to this?

In my opinion completely adopting one countries legislation would not be a viable solution.

5.4.7 *Analysis Of The Data*

From the analysis of the data we can deduct in to the following conclusion.

- Most of TK holders need legal protection.
- Their customary law should also taken into account while considering the matter of protection
- They are not against the accessing of TK by third parties. But that should be in a sustainable manner. Most of the time over exploitation also affecting adversely the very existence of that particular knowledge. and it is important to note that many of the tribes are dependent on their Traditional knowledge.
- Most of the TK holders are illiterate so it's very difficult for them to appreciate the nuances of IPR law and its implication upon them. So they need a help from the part of government to help and understand the law concerning with them.
- It is very interesting to know that they are not against granting of patent right to a person/ company , who really invented something new and useful, even though the basis of it was from a traditional knowledge.

CHAPTER VI

CONCLUSION

The commercial value of traditional medicinal knowledge is increasing day by day. Civilized society realized the efficacy and appropriateness of the traditional medicinal knowledge todays life. Most of the developing countries are having great an amount of traditional knowledge which is highly helpful for the entire human civilization. We could see a revolution on a world wide scale has come to recognize the importance of these traditional medicinal knowledges. Since it is related to the rights of the indigenous community and their identity many governments took a positive action to protect their TK. Some of them took a step ahead to protect the TK on sectoral basis. China and Thailand are some of the examples.

But it is difficult to say which model would be the best model to protect TK. As we have seen already every model has its own merits and demerits, however all these models have contributed to the jurisprudential aspect of protection of TK in its own ways. So one can at the most tell what would be the most viable solution to protect the TK on the country. We should address the specific need of a country while framing the sui generis model of that country, than going for a sui generis model which will suit in all countries of the world. similarly while framing the sui generis model law for a country , a reasonable doubt may arise as to a sectoral protection of TK is needed ? here also answer would not be same in all countries. Since the world communities are diverse in nature and in needs their laws and approach also tend to be different.

6.1 SECTORAL PROTECTION VS COMPREHENSIVE PROTECTION

However considering the geographical and cultural condition of India, it would advisable for the Indian government to frame a sui generis model specifically for the protection of traditional medicines. Government should realize the value of traditional medicines that are existing among the indigenous community living in the various parts of the India in general, and in particularly southern and north east part of the India. As far as India is concerned sectoral protection of TK specifically for traditional medicines are great in need as its sustainable commercialization promotes the foreign currency to the Indian economy as well as it protection against missappropriation will protect the rights of indigenous community and the constitutional principles enshrined in the various article of the constitution of India. The diverse nature of TK also justifies the sectoral protection of TK.

6.2 NATIONAL LEGISLATION OR A STATE WISE LEGISLATION

India should frame a national legislation for the protection of Traditional medicine. As we have already seen kerala government's attempts to protect it traditional medicine knowledge, still the constitutionality of such legislation will be unresolved.

The Kerala Intellectual Property Policy, 2008 is a very important step towards the protection of traditional knowledge. However, intellectual property being a matter enumerated in the union list, the basic power behind bringing such legislation has been jeopardized. However, if an umbrella policy similar to the one brought by the Kerala government can be formulated by the union government, it will be a landmark for the protection of the rights of the tribal people across the country.

Such a policy would not only allow the exploitation of the traditional medicinal knowledge commercially, but also provide protection in cases of gross misappropriation of traditional knowledge, where the same does not fall within the ambit of knowledge of commons. This is one of the grey areas against which even the Kerala Intellectual Property Policy, 2008 fails to provide. Such an infirmity in my opinion can be cured only when there is a central legislation to that effect, which can provide protection to the traditional knowledge in cases where the same has be patented under the Indian Patents Act, and against which the remedy lies only in the Indian Patent Act and not in any IP Policy.

6.3 DEFINITION OF TRADITIONAL MEDICINE:-

Though defining traditional medicine is not necessary for giving protection. but the approach which has taken by the china and Thailand will be apt in Indian situation also. While defining the term it should not be restricted unnecessarily. Further more traditional medicine should include all practices, method, usage, preparation, formula, or any combination which used by or invented by any one or more members of the family, community or communities and transmitted through generation to generation. As an explanation to this section we could add the cosmetic preparation also will come under the term traditional medicinal knowledge.

6.4 PROTECTION AGAINST MISAPPROPRIATION

There should be a provision for protection against misappropriation. There definition that WIPO have suggested, could be use in the legislation with appropriate changes, WIPO defined the act of misappropriation as follows

"Specific acts of misappropriation:Acquisition of TK by theft, bribery, coercion, breach of contract,misrepresentation, etc Defensive protection of TK Acquisition of TK in violation of prior informed consent Commercial use of TK without equitable compensation or benefit benefit-Sharing Other acts of unfair competition"

But Considering the India's literacy rate and the economical vulnerability of the indigenous people in India, they tend to get influenced by the false deal of the corporation; therefore we should incorporate the component of "undue influence" into the definition of 'act of misappropriation'.

6.5 COMMUNITY PARTICIPATION

There should be a provision for community participation in all matters related to their traditional medicinal knowledge. Especially while making decision on the access and benefit sharing mechanism. If there anything which is violative of the customary law and practice of that community then that should be taken into consideration before giving consent to access and commercialization of that traditional medicinal knowledge. There should be a provision for respect and recognize the customary law of the communities.

It is very important to incorporate the prior informed consent and the consent for accessing of the traditional medicinal knowledge should emancipate from the community concerned. It should not be transformed to any governmental agencies. A vast country like India, setting up of administrative machinery and vesting with the power to give consent for accessing traditional medicinal knowledge is not a reasonable thing. That particular community can only assess how important a

particular traditional medicinal knowledge is. Therefore sitting in a far place and decide up on the matter related to other corner of the country will not be always just and fair. Nevertheless, government machinery can act as a good platform for facilitating the negotiation between the commercial exploiter and the community.

6.6 RECOGNITION OF THE RIGHT OF THE TRADITIONAL KNOWLEDGE HOLDERS

There should be recognition of the right of the traditional medicinal knowledge holders over their traditional medicinal practices. From the filed study researcher could able to gather that they are not in favor of giving any exclusive right over their property to any certain person or an entity. Therefore one of the viable way is that there should be a provision as to traditional communities can use their knowledge for their personal uses as seen in many other countries around the world. However when it comes to patenting of the traditional medicinal knowledge the same should be prohibited.

But there may be a reasonable question arise will it un necessarily restrict our research. To address this issue we should add a provision where it grants a limited term of patent of six or eight years to the entity which come up with a new invention but based on the traditional medicinal knowledge. But here also conditions and parameters should be lay down for applying such kind of patent. It should not be left open to the discretionary power of the court whether it is completely a new invention.

6.7 DURATION OF THE PROTECTION

Protection of TK against misappropriation should be for unlimited term.

6.8 PLATFORM FOR NEGOTIATION

We should address a main issue that most of the communities are illiterate. So it is not advisable to leave the communities for negotiation with big corporation, it will adversely affect their interest as there was no power parity. So negotiation should be done between the persons appointed for the each side. And community should give a right to choose any person they wanted to conduct negotiation on behalf of them. The cost incurred should be paid by the government. However before entering into the negotiation terms should be informed to the communities and community can revise the terms and decide whether they should enter in to it or not. The negotiation process should record as document.

6.9 CONSTITUTION OF ADMINISTRATIVE BODIES

There should be a provision for the constitution of administrative bodies, but those bodies should not be constituted in far places. There should be local bodies entrusted with the power of protection of traditional medicinal knowledges.

6.10 CONSERVATION OF TRADITIONAL KNOWLEDGE

There should be a provision which stipulates all the commercial exploiters has a duty to cultivate certain medicinal plants of their own. Government should fix the amount of medicinal plants that can be used by a commercial exploiter per annum.

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ANNEXURE

(Questionnaire for AVS, kotakkal)

1. Could you please explain the method of herbal collection?
2. Could you please relationship between the Muslim herbal collectors and the Arya Vaidya Sala?
3. Are these Muslim herbalist contributed in to your medicinal knowledge?
4. Is there any mechanism through which Arya Vaidya Sala sharing its benefits with local tribes people?

   If yes, can you throw some light on the benefit sharing mechanism of Arya Vaidya Sala ?

5. Do the local people participate in the herbal collection?
6. What is the source of medicinal knowledge of the Arya vaida sala , is it only from 'Veda' or the Arya Vaidya Sala has taken help from other local and traditional sources ?
7. In your opinion what are the problems faced by the traditional Indian medicinal knowledge holders?
8. What is your opinion about TKDL in Kerala? Will it solve the problems of misappropriation of TK?
9. Are you aware of kerala Intellectual property policy 2008? Do you think that it will afford better protection of TK?
10. Would traditional IPR provide an effective protection?
11. Would 'sui generis' model be a good alternative?
12. Our understanding of sui generis is the models provided by the WIPO, china, and Thailand. In your opinion what changes do you suggest to this?