TRADITIONAL MEDICINE AND INTELLECTUAL PROPERTY RIGHTS: BASIC ISSUES

Dissertation Submitted to Jawaharlal Nehru University in Partial Fulfillment of the Requirements for Award of the Degree of

MASTER OF PHILOSOPHY

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DECLARATION

I declare that the dissertation entitled **"TRADITIONAL MEDICINE AND INTELLECTUAL PROPERTY RIGHTS: BASIC ISSUES"** submitted by me in partial fulfillment of the requirements for the award of the degree of **MASTER OF PHILOSOPHY** of Jawaharlal Nehru University is my own work. The dissertation has not been submitted for any other degree of this University or any other university.

S. Swarna Latha

CERTIFICATE

We recommend that this dissertation be placed before the examiners for evaluation.

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Supervisor

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TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

ABBREVIATIONS

AYUSH	:	Department pf Ayurveda, Yoga, Unani, Sidha and Homeopathy
BDA	:	The Biological Diversity Act, 2002
CAM	:	Conventional and Alternative Medicine
CBD	:	Convention on Biological Diversity, 1992
CCRAS	:	Central council for Research in Ayurveda and Sidha
CCRH	:	Central Council for Research in Homeopathy
CCRUM	:	Central Council for Research in Unani Medicine
CCRYN	:	Central council for Research in Yoga and Naturopathy
CSIR	:	Council of Scientific and Industrial Research, India
COST	:	European Cooperation in the field of Scientific and Technical research
COP	:	Conference of Parties
CTE	:	Commission on Trade and Environment
EU	:	European Union
EPO	:	European Patent Office
EMEA	:	European Agency for the Evaluation of Medicinal Products
FAO	:	Food and Agricultural Organization
HCC Act 1973	:	Homeopathy Central Council Act, 1973
HIV/AIDS	:	Human Immune Virus/Acquired Immune Deficiency Syndrome
GOI	:	Government of India
IK	:	Indigenous Knowledge
ILO	:	International Labour Organization
IMCC Act, 1970	:	Indian Medicines Central Council Act, 1970
IPC	:	International Patent Classification
ISM&H	:	Indian Systems of Medicine and Homoeopathy
IPRs	:	Intellectual Property Rights
LHT	:	Local Health Traditions
MNC	:	Multi National Corporations
NCCAM	:	National Center for Complementary and Alternative Medicine
NBA	:	National Biodiversity Authority
NGO	:	Non-Governmental Organization
NMPB	:	National Medicinal Plants Board
OAU	:	Organization of African Union
PAA	:	Patents (Amendment) Act, 2005
PCT	:	Patent Cooperation Treaty
PIC	:	Prior Informed Consent
SAARC	:	South Asian Association for Regional Cooperation
TCM	:	Traditional Chinese Medicine
TK	:	Traditional Knowledge

TKDL	:	Traditional Knowledge Digital Library
TKRC	:	Traditional Knowledge Resource Classification
TM	:	Traditional Medicine
TMP	:	Traditional Medicine Program
TMS	:	Traditional Medicine Strategy
TRIPS	:	Trade Related Intellectual Property Rights
UDHR	:	Universal Declaration of Human Rights
UK	:	United Kingdom
UNCTAD	:	United Nations Commission on Trade and Development
UNEP	:	United Nations Environment Program
UNICEF	:	United Nations Children's Educational Fund
UNFCCC	:	United Nations Framework Convention on Climate Change, 1992
USA	:	United States of America
USPTO	:	United States Patent and Trademark Office
UPC	:	Unani Pharmacopoeia Committee
WCED	:	World Commission on Environment and Development
WHCAM	:	White House Commission on Alternative Medicine
WHO	:	World Health Organization
WIPO	:	World Intellectual Property Organization
WIPOCIPR	:	WIPO Commission in Intellectual Property Rights
WTO	:	World Trade Organization

CHAPTER I

CHAPTER I

INTRODUCTION

Traditional Medicine (TM) is widely practiced in most of the developing countries. Even to this day it plays a crucial role in health-care and serves the health needs of a vast majority of people in these Countries. The World Health Organization (WHO) points out that in Africa up to 80 per cent of the population use TM to meet health care needs (WHO-TMS 2002:1). In Asia and Latin America, populations continue to use TM as a result of historical circumstances and cultural beliefs.[1] In India around 70 per cent of population depends on the TM for their health needs. In China, TM accounts for around 40 per cent of all health care annually delivered. Even in the developed countries there is growing demand for the traditional and Complementary/Alternative Medicine (CAM). According to WHO Report, for example people in Australia, Canada, USA, Belgium and France in way or the other use CAM (WHO-TMS 2002:2).[2]

TM becomes the only affordable treatment available to poor people where access to modern health care services and medicine is limited for various economic, social and cultural reasons.[3] According to the WHO, TM serves the health needs of almost 80 per cent of people in the developing countries, where access to "modern" health services and medicine is limited by economic and cultural reasons. The broad use of TM in the developing countries is because of its accessibility and affordability. For example, in Uganda, the ratio of TM practitioners to population is between 1:200 and 1:400. This contrast starkly with the availability of allopathic practitioners, for which the ratio is typically 1:20 000 or even less (WHO -TMS 2002:12).

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[1] According to a report by the WHO, all kinds of TM are used in almost 80-90 percent of Asian Countries. In Latin American Countries also the utilisation of TM/Herbal medicine accounts approximately to 60 per cent (Ong 2005:46).

[2] TM/CAM is used at least once is 48 per cent in Australia, 70 per cent in Canada, 42 per cent in USA, 38 per cent in Belgium and 75 per cent in France (WHO-TMS 2002:2).

[3] It is observed that, in the countries like Ghana, Kenya and Mali, research has shown that a course of the pyrimethanine/sulfadoxine anti-malarials can cost several dollars. Yet per capita out–of–pocket health expenditure in Ghana and Kenya amounts only around US$ 6 per year. Conversely, herbal medicines for treating malaria are considerably cheaper and may sometimes even be paid for in kind and according to the "wealth" of the client. TM is also highly popular in many developing countries because it is firmly embedded within their wider belief systems (WHO-TMS 2002:13).

I.1. Traditional Medicine in the Global Context: Some Facts

TM as mentioned earlier that it is some times the only affordable source of health care – especially for the world's poorest patients, also in these countries the consumption of TM is considerably more than the modern medicine/allopathic medicine.[4] A 1991 survey by the US Agency for International Development found that, in Sub-Saharan Africa, traditional practitioners outnumber allopathic practitioners by 100 to 1. It should be noted that situation has not changed even in recent times. For example, surveys conducted by the WHO Roll Back Malaria Programme in 1998 showed that in Ghana, Mali, Nigeria and Zambia, more than 60 per cent of children with high fever are treated at home with herbal medicines. Malaria treatment in Ghana with herbal medicines is noticed to be considerably cheaper than the other forms of health care wherein the cost of the clinical medicine accounts to US$ 1.60 and the cost of the self treatment with herbs range from US$ 0.35 – 0.10. Similarly in Salvador, the fee for treating a child for diarrhea as an out-patient at a public hospital — including consultation fee and medication — can be as high as US$ 50. Treatment by a TM practitioner may be no more than US$ 5 or payable in kind. One of the key reasons cited for this was the ready accessibility of herbal medicines in rural areas (WHO-TMS 2002:13).

Studies also showed that most of the Africans living with HIV/AIDS use traditional herbal medicines to obtain symptomatic relief and to manage opportunistic infections. Frequently, TM practitioners are well known in their communities for their expertise in health care and prevention of many sexually transmitted diseases. A recent survey by UNAIDS also showed that 78 per cent of patients living with HIV/AIDS in the USA use some form of CAM for their treatment. UNAIDS is therefore advocating collaboration with TM practitioners in AIDS prevention in the sub-Saharan Africa and it was categorically pointed out that "traditional medicine is in a real sense carrying the burden of clinical care for the AIDS epidemic in Africa. This trend has been largely overlooked by health ministries and international agencies" (WHO-TMS 2002:14).

[4] For instance, the per capita consumption of TM products in Malaysia is more than double the consumption of modern pharmaceuticals. TM is even significant in relatively advanced developing countries such as South Korea, where the per capita consumption of TM products is about 36 per cent more than the modern drugs (Balasubramanian 1997:3).

As mentioned earlier, TM is increasingly becoming popular in the developed countries and there is an increasing demand for TM, the drug industries are now engaged in coming with varieties of herbal medicines with the name of CAM. For this reason, protection of TM is assuming importance and urgency. Many pharmaceutical products produced and used in the developed countries are based on, or consist of, biological materials sourced through reference to traditional medicine. These include compounds extracted from plants and algae, as well as from microbial sources and animals. Plants, in particular, are an indispensable source of pharmaceuticals. The demand for "herbal medicines" has grown dramatically in recent years. The world market for such medicines has reached, according to one estimate, US$60 billion, with annual growth rates of between 5 and 15 per cent (WHO-TMS 2002:12). It is also noticed that in many parts of the world expenditure on TM/CAM is not only significant, but growing rapidly. In Malaysia, an estimated US$ 500 million is spent annually on this type of health care, compared to about US$ 300 million on allopathic medicine. In the United States of America (USA), total 1997 out-of-pocket CAM expenditure was estimated at US$ 2700 million. In Australia, Canada and the United Kingdom (UK), annual CAM expenditure is estimated at US$ 80 million, US$ 2400 million and US$ 2300 million respectively (WHO-TMS:12).

In the developed countries it is noticed that funding and establishment of CAM research and research units at sites of research excellence is likewise increasing.[5] Based

[5] In the United Kingdom, the National Health Service recently funded two trials of Acupuncture for treating chronic pain, while in Germany; a centre for CAM research at the Technische Universität in Munich has produced a series of important systematic reviews. In the USA, in 1992, US Congress established the Office for Alternative Medicine in the National Institutes of Health (see http:// nccam.nih/gov/). The mandate of this Office was extended in 1999, with the Office becoming the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM has received progressive budget increases — by 2000, its budget had risen to US$ 68.4 million. Concurrently in 2000, the White House set up the White House Commission on Alternative Medicine (WHCAM) Created by an executive order on 8 March 2000, the Commission is charged with developing a set of legislative and administrative recommendations to maximize the benefits of CAM for the general public. The USA also has a large number of units for CAM research, based at research institutions such as the University of Maryland, Columbia University in New York, Harvard University in Massachusetts, and the Memorial Sloan- Kettering Cancer Center in New York.43 International activity in TM/CAM is also becoming more prominent. The European Union (EU) recently completed a COST (European Cooperation in the field of Scientific and Technical research) project on "unconventional medicine". And in a 1999 EU Parliamentary Assembly (entitled *A European Approach to Non-conventional Medicines*), Member States were called upon to promote official recognition of CAM in medical faculties, to encourage its use in hospitals, and to encourage allopathic doctors to study CAM at university level. Also in Europe, the European Agency for the Evaluation of Medicinal Products (EMEA) works on the quality, safety and

on the growing importance for TM in both the developed and the developing countries it is estimated that the relevance of the TM in developing countries may increase in the future because of the persisting poverty and marginalization and also because of the high prices generally charged for the patented medicines (Correa 2001:1).[6] The increasing trend in transferring TM-related knowledge from developing to developed world is another issue which needs consideration.

I.2. Traditional Medicine and India

The preservation and protection of TM is crucial for India as it has a rich, centuries-old heritage of traditional health care systems. Ayurveda and Yoga date back approximately 7000 years. These systems have survived due to their strengths and the efficacy of their drugs and treatments which have taken care of the health needs of the people. The Indian government has recognized the codified traditional systems- Ayurveda, Sidha, Homeopathy and Unani – as well as the non-drug therapies such as yoga and naturopathy.

Public health is a core issue in India. In the last two decades the country has seen an increase in newly-emerging diseases which have greatly changed the morbidity and mortality scenario. Major contributors to national mortality and morbidity are communicable diseases such as HIV/AIDS, tuberculosis, malaria, kala-azar etc, as well as lifestyle-related and chronic diseases such as nutritional deficiencies, diabetes, ischaemic heart disease, cancer and certain problems of reproductive and childhood diseases. Regardless of good infrastructure for allopathic - primary, secondary and tertiary health care, approximately 70 per cent of the population uses TM for primary health care needs. There is sufficient awareness and demand for these systems that they are used alongside, or sometimes in preference to allopathic health care. Rural populations usually prefer Ayurveda, Siddha and Unani medicines and therapies (Bodekar et al, 2005:89).

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efficacy of herbal medicinal products. An Ad Hoc Working Group on Herbal Medicinal Products was also established by the EMEA in 1997 (WHO-TMS 2002:18).

[6] The TRIPS Agreement has imposed the obligation to recognize product patents for pharmaceuticals in all Members to the World Trade Organization. On the impact of TRIPS Agreement on the developing countries, see generally, Chimni (1993); Utkarsh et al (1999).

Traditional health care systems offer a wide range of safe, cost effective, natural therapies, which can be used alone or in conjunction with allopathic health care. Because of this, these systems and therapies are used to a large extent to meet the health care needs of the populations. As a result of the systematic developments and improvements, these systems are now being used more widely by the public at national and international levels.[7] Therefore India foresees a greater role for the ISMs and their practitioners in achieving targets for health care. For this India has adopted policies to mainstream and integrate the ISMs in to the national health care programmes and the health care-delivery systems. Efforts are also being made to improve the quality and standards of education, drugs and health services. Priority is given to the scientific validation, in accordance with modern scientific parameters in order to develop traditional medicinal products acceptable to the international market. Apart from these India also had to take measures to defy the challenges in the form of "biopiracy" posed by the current intellectual property systems.

I.3. Traditional Medicine and Biopiracy

Biopiracy has been described as "the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized countries" (Shiva, 2001:49). In simple terms biopiracy is understood as the appropriation of the knowledge which is in the public domain and mostly held by the indigenous and local communities by individuals or institutions located outside these systems seeking exclusive monopoly control (usually patents) over these resources and knowledge.

Biopiracy has an intrinsic link with IPRs. In other words, IPRs are employed as a tool to legitimize the fruits of TK/TM. Biopiracy can be committed in many ways. For example, if patents are granted for the inventions that are neither novel nor inventive having their origin in traditional knowledge (TK) already in public domain. Such patents may be granted either due to oversights during the examination of the patents or simply because it is written down but not accessible, or available to the examiner, or because it is

[7] In the USA, herbal sales increased by 101% in mainstream markets between May 1996 and May 1998. The most popular herbal products include ginseng, *Ginkgo biloba*, garlic, *Echinacea* spp. and St. John's wort (WHO-TMS 2002:12).

unwritten knowledge. Or in some cases patents may be correctly granted according to national laws on inventions derived from a community's TK or genetic resources. But this could constitute 'biopiracy' on the following grounds: patenting standards are too low; patents are allowed, for instance, for inventions which amount to little more than discoveries. Alternatively, the national patent regime may not recognize some forms of public disclosure or TK as prior art.[8] Even if the patent represents a genuine invention, however defined, no arrangements have been made to obtain the prior informed consent (PIC) of the communities providing the knowledge or resources, and for sharing the benefits of commercialization to reward them appropriately in accordance with the principles of the Convention on the Biological Diversity, 1992.

Cases of biopiracy extend to the subterranean world, possibly the most fertile and diverse region of the world, with one small bag of soil potentially containing more species than an entire tropical rainforest (Stenton 2004:18). However, biopiracy is not only restricted to the exotic vegetation and soils, it also encompasses rare and highly toxic animal species and even more alarmingly, indigenous people themselves.[9]

Scholars argue that the contemporary phenomenon of biopiracy continues to be justified through a variety of legally biased rules founded on Western high-level and non-discriminatory patent regime (Stenton 2004:17). The patenting of the TMs are justified by the glaring fallacy and inherently biased western perception that, because significant financial resources have been invested in refining the original material, scientific trials and chemical analysis, the product has been improved and should be regarded as novel. A critique of this interpretation is advanced by Carlos M. Correa, who suggests that in reality, drug companies do not actually do that much in converting the raw material in the final product (Stenton 2004:19). With some 80 per cent of the world's biological diversity lying in the tropical and sub-tropical regions of the South, that around 40 per

[8] For instance. Article 102 & 104 of the Act 35 of US.

[9] Tissue and blood samples are regularly exported from developing countries for research into a particular field, and are then often abused when they are found to have properties that may prove useful in another field of medicine leading to a multi-million dollar pharmaceutical product. A classic example of this kind of biopiracy: While examining members of the Pandilla people of North and South America, the research team lead by Darrel Posey and Graham Dutfield on Rural Advancement Foundation International (RAFI) of Canada reported that doctors had discovered a local woman who had immunity to leukemia. The immunity gene was immediately isolated and a patent was sought (Raghavan 2001:9).

cent of Western pharmaceutical products are found to contain Asian plant extracts alone and 56 percent of the top 150 prescribed drugs in the United States are based on chemicals derived from plants. The existence of a world market for herbal medicines is estimated at $43 billion with an annual growth rate of 5 per cent, the potential economic rewards for the undeveloped world are enormous, as is the temptation for pharmaceutical companies to commit acts of biopiracy.

The effects of biopiracy are perceived to be ill and are mostly described as the "plunder of nature", an "epidemic" etc. (Shiva V 2003). Biopiracy and patenting of indigenous knowledge are considered as double theft because first it allows theft of creativity and innovation, and secondly, the exclusive rights established by patents on stolen knowledge steal economic options of everyday survival on the basis of the biodiversity and indigenous knowledge. The increasing number of biopiracy cases has alarmed for a need to protect the traditional knowledge system through an international instrument. Recently, a US based Indian, Bikram Choudary has applied for a patent of Yoga practiced in a steam room. Till now USPTO is learnt to have issued 150 Yoga related copyrights, 124 trademarks on Yoga accessories and around 2315 Yoga trademarks so far (Sidharta 2007:1). It is more disturbing situation, that even after the traditional knowledge systems especially Ayurveda, Siddha and Yoga have been codified in the form of data base known as "traditional knowledge digital library" (TKDL) which is placed at the disposal of the international patent examiners, the instances of granting of the IP rights on the prior art are ever increasing in number.

I.4. Traditional Medicine and IPRs

The efforts to provide an IPR-dimension to TK and TM at the multilateral level began at the Doha Ministerial Conference of the WTO in 2001. Para 19 of the *Doha Declaration, 2001* expanded the ambits of the Agreement on Trade Related Intellectual Property Rights (TRIPS), in particular Article 27.3 (b) and mandated the TRIPS Council to review the implementation of the TRIPS Agreement under Article 71.1 and to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), 1992 the protection of TK and folklore, genetic resources and other developments.

The debate has triggered the issues of linkages between Article 8(j) of the CBD and Article 27 of the TRIPS Agreement and also about the countries obligations of implementation under these international treaties through national legislations. In the TRIPS Agreement, there is nothing that specifically prevents countries from developing systems to protect TK at the national level. During the Doha negotiations developing countries have made a number of proposals to the TRIPS Agreement to incorporate provisions related to the protection of TK and avoidance of misappropriation. India made a proposal to make it obligatory in all patent applications for biotechnological innovations, for the disclosure of origin and to make it obligatory to indicate whether prior informed consent was obtained for the biological genetic resource or traditional knowledge so as to facilitate benefit-sharing arrangements. A *sui generis* system of protection was proposed by the African group. The developing countries such as Brazil and India also have underlined the need to explore *sui generis* system for the protection of TK. On the other hand the developed countries held the view that the TRIPS Agreement and the CBD are mutually supportive and objected to the idea of disclosure requirement of genetic resources in the process of patent applications.

In order to implement CBD, countries like Brazil, India, Peru, Philippines and Thailand have brought legislations providing protection to TK through a combination of various systems.[10] There are also some attempts to have guidelines and model provisions through regional arrangements in Asia and Africa in the recent years. These legislation and model agreements contain provisions for prior informed consent, benefit sharing, some restrictions on applying for IPRs based on biological resources and associated TK without PIC and protection through various other means like registration of TK, systems of contract, recognition of customary laws, etc. However, the actual measures provided or proposed are different in each country and are considered inadequate to protect TK. It is observed that there is no uniformity in the provisions and each country's legislation is developed based on the specific requirements of individual country and its communities, their lifestyles and types of traditional knowledge and the way it is being protected or

[10] The Countries like Bangladesh, Pakistan, Bhutan and Sri Lanka are in the process of enacting or enforcing the legislations for the protection of knowledge of the communities (indigenous) and access to genetic resources.

held by the traditional communities and the way it is being accessed for modem scientific purposes.

In India, enabling provisions have been made for protecting the traditional knowledge in the Biological Diversity Act, 2002 (BDA) and the Patent (Amendment) Act, 2005. The BDA requires the prior authorization of the National Biodiversity Authority (NBA) for access to the biological resources associated with traditional knowledge and traditional medicines or biosurvey or for any IPR protection. On the other hand, the Patents (Amendment) Act, 2005 (PAA) prohibits patenting of the inventions which are based on the prior art of India or elsewhere. Mechanisms such as pre-grant oppositions and revocation proceedings are provided under the PAA. But, since the IPR laws are applicable only within the state which has enacted it, the Indian Patent Act does not prevent Indians from claiming IPR protection in another country for the knowledge that has its origin in other countries. Even the BDA also does not prevent from making applications for IPRs for inventions based on the prior existing knowledge or information of biological resources obtained from other countries. The lack of uniformity among the national legislations with regard to protection of prior art and knowledge is also a cause for increasing cases of bio-piracy.

The relevant issues associated with the protection and promotion of TK therefore could be summarized as under: Defining the TK and TM; Determination of the subject matter of TK for protection; Systems of protection of TK; Prevention of bio-piracy and misappropriation of TK; and means for fair and equitable sharing of benefits arising out of utilization of biological resources associated to TK.

I.5. Statement of Problem

According to the WHO, TM serves the health needs of almost 80 per cent of people in the developing countries, where access to "modern" health services and medicine is limited by economic and cultural reasons. As TMs are largely based on medicinal plants, indigenous to these countries, where the system has been in vogue of several centuries, the effort is now on accessing them either directly or through the use of modern tools of breeding and cultivation, including tissue culture, cell culture and transgeneric technology. According to the All India Coordinated Research Project on Ethnobotany, the indigenous communities are acquainted with the use of over 9000

species of plants and specifically for the purpose of healing they know the use of over 7500 species of plants. The global market for herbal products, with its appeal ranging from pharmaceuticals and health foods to cosmetics, toiletries and ethnic products, is estimated to touch US $ 5 trillion by 2020 (SRISTI website).

The protection of TM under IPRs raises two types of issues. First, to what extent is it feasible to protect TM under the existing IPR system? Certain aspects of TM may be covered by patents or other related IPRs. Secondly, there have also been many proposals to develop *sui generis* systems of protection, the system of sharing of benefits and the prior informed consent. Such proposals are based on the logic that if innovators in the 'formal' system of innovation receive compensation through IPRs, holders of traditional knowledge should be similarly treated.

Since there are codified systems of 'traditional medicine' and non-codified medicinal knowledge, which includes 'folk', 'tribal' or 'indigenous' medicine and they are practiced/administered by performing various rituals, there is still a controversy as to the subject matter of protection. In India, for example, folk traditions are handed over orally from generation to generation. The 'folk' medicine is based on traditional beliefs, norms and practices based on century's old experiences of trial and error, successes and failures at the household level. These are passed through oral tradition and may be called, "people's health culture", home remedies or folk remedies. TM may be possessed by individuals. In some cases, for instance, healers use rituals as part of their traditional healing methods, which often allow them to monopolize their knowledge, despite disclosure of the phyto-chemical products or techniques used. The codified tradition consists of medical knowledge with sophisticated foundations expressed in thousands of manuscripts covering all branches of medicine. Examples are Ayurveda, Siddha, Unani and the Tibetan tradition. It is therefore argued that the current legal framework of IPR seems to be not suitable to protect this knowledge of the traditional communities. The study therefore is proposes the following objectives.

I.6. Objectives of Study

- To examine the scope and definitional aspects of traditional knowledge and traditional medicine with specific focus on the concerns of the developing countries.
- To examine whether TM satisfies the requirements of patentability under the existing intellectual property norms.
- To examine the developing and developed countries negotiating positions on TM and TK.
- To examine the regional and national initiatives for the protection of TM, and
- To examine the Indian practice, policy and regulations in this area.

I.7. Scope of the Study

The scope of the study is limited to the examination of the basic issues regarding the protection of TM. Issues of defining TM and TK, reasons for the need of protection, determination of the subject matter of protection are examined by considering the available literature. The study has essentially focused on the issues of protecting TM and the negotiations that are carried under different national and multilateral fora. The study has also examined the Indian practice and regulations separately.

I.8. Hypothesis

The study is based on the hypothesis that the current negotiations on the protection of TK and TM need to be focused on a *sui generis* model. The existing approach, specifically enumerated by the developed countries, to bring TM under the ambit of IPRs may not be suitable. The existing legal framework for the protection of TK and TM therefore, appears to be inadequate and needs to be remodeled in order to sufficiently accommodate the legal interests of TK holders.

I.9. Research Questions

- What is TM? And why it needs protection?
- What are the perspectives of the developing and the developed countries?
- Whether the intellectual property could be an effective tool to protect TM?
- Whether the *sui generis* system would be an effective option for protecting TM?
- How effective the options of benefit-sharing, prior informed consent, and to maintain the database of the TK would be?

I.10. Outline of the Study

The study has six chapters. The first chapter introduces the background of the problem of biopiracy. It highlights the importance of TM in India and world wide. It also describes the role of TM in India. It describes the scope, hypothesis, objectives and research questions of the study.

Second chapter attempts to analyze the basic issues related to TM. While describing various systems of TM practiced worldwide and their importance in the national health care systems wherever they are practiced, the chapter describes the nature, scope and subject matter of TM for the purpose of protection. Some basic questions as what is traditional about TM, whether it codified or oral and the ownership of TM are also analyzed.

In the third chapter, the definition of TM and also the TK is critically analyzed. The emerging concerns, reasons and justifications for protecting TM in correlation with the domain of IPRs are critically examined. The chapter also describes various reasons of protecting TM. In this chapter, the basic issue of whether TK and TM fulfill the requirements of patentability as provided under the existing intellectual property norms is attempted to answer. An analysis of the scope and application of the IPRs with specific reference to "public domain" issues are also dealt with.

The fourth chapter will discuss the compatibility of the current IPR regime for protecting TM. The Chapter will also discuss evolution of the existing international frame work under the TRIPS and CBD which provides for the protection of TK & TM. Finally it analyzes the negotiating strategies of the countries at WTO, WIPO and CBD and the models of protection proposed.

The fifth chapter exclusively focuses on the regulation of TM in India. The chapter analyzes the Indian initiatives for the protection of the TM in response to its international obligations and also in response to the challenges of Biopiracy.

The Concluding chapter attempts to provide conclusions and some suggestions for effective the protection of TM.

I.11. Research Methods

The study has been carried out by employing historical and analytical methods. Survey of the jurisprudence available on the issue, specifically with regard to the definition and legal status of TK and TM are made in the first part of the study. The study focuses on the TM, with specific reference to concerns of developing countries, including India. The literature on Ayurveda, Sidha, Unani and Yoga will also form part of this study. Database of TK made by several ethnobotanical organizations and the literature available in various national and international journals, Government websites and of various international organizations are also consulted wherever necessary.

CHAPTER II

CHAPTER II

TRADITIONAL MEDICINE: MEANING AND SCOPE

II.1. What is Traditional Medicine?

Traditional Medicine (TM) is generally referred to the diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being (WHO-TMS 2002:7). It is also widely understood that TM is that kind of medicine which is different from the so called 'modern' or 'scientific medicine'.[1] The comprehensiveness of the term "traditional medicine" and the wide range of practices it encompasses make it difficult to define or describe in precise terms. It is observed that traditional medical knowledge may be passed on orally from generation to generation, in some cases within families specializing in specific treatments, or it may be taught in officially recognized universities. Sometimes its practice is quite restricted geographically, and it may also be found in diverse regions of the world. However, in most cases, a medical system is called "traditional" because of the way it was acquired, used and transmitted and when it is practised within the country of origin (WHO 2001:2).

TM is differently described by different states and it is also observed in the literature that TM is often referred with other related terms such as: complementary or alternative medicine; traditional medicinal knowledge[2]; herbal medicine; indigenous medicine or folk medicine or tribal medicine, etc. In the following a brief description of the related terminology of the traditional medical systems practiced worldwide has been outlined.

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[1] The Modern or Scientific Medicine is popularly known as allopathic or western or biomedicine and is considered by the developed countries as systematic compared to the TM. "Biomedicine" is defined in the Traditional and Alternative Medicine Act, 1997 of Philippines as "...discipline of medical care advocating therapy with remedies that produce effects differing from those of the diseases treated. It is also called 'regular medicine', 'conventional medicine', 'mainstream medicine', 'orthodox medicine', or 'cosmopolitan medicine' (WHO 2001: 1).

[2] The WHO refers to the traditional medicine as traditional medical knowledge under which it recognizes all the traditional medicinal systems widely practiced worldwide (WHO TMS 2002).

a) Complementary and Alternative Medicine (CAM)

In most of the developed countries, the terms like complementary or alternative medicine (some times non-conventional) are used to refer to a broad set of health care practices that are not part of a country's own tradition, or not integrated into its dominant health care system (WHO-TMS 2002:7).[3] The WHO refers to the TM of the Europe, North America and Australia as CAM. As the terms 'complementary' and 'alternative' suggest, they are sometimes used to refer to health care that is considered supplementary to allopathic medicine. However, this can be misleading. According to the reports of the WHO, in some countries, the legal standing of CAM is equivalent to that of allopathic medicine. Many practitioners are certified in both complementary/alternative medicine and allopathic medicine, and the primary care provider for many patients is a complementary/alternative practitioner. Studies show that use of CAM is increasing rapidly in the developed countries (WHO 2001:1).

b) Herbal Medicine

Herbal medicines[4] are defined by WHO as "finished, labelled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant material, or combinations there of whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including the isolated constitutes of plants, are not considered to be herbal medicines. Exceptionally, in some countries herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin (WHO 1996:178). Herbal medicines are used in almost all systems of TMs worldwide. Reports show that

[3] For instance, Acupuncture is a traditional Chinese medicinal therapy and is widely practiced in the Western Countries. But many European countries define it as CAM, because they co not form part of their own health care traditions. Similarly, since homeopathy and chiropractic systems were developed in Europe in the 18th Century, after the introduction of allopathic medicine, they are not categorized as TM systems and are also not incorporated into the dominant modes of health care in Europe. Instead they are regarded as a form of CAM (WHO-TMS 2002:8).

[4] Herbal products are the end products of the herbal preparations which are produced by subjecting herbal materials to extraction, fractionation, purification, concentration, or other physical or biological processes. They may be produced for immediate consumption or as the basis for herbal products (WHO 2001:1).

they are used in TCM, Ayurveda, Unani, Naturopathy, Osteopathy, Homeopathy and others indigenous systems of medicine (WHO-TMS 2002:8).

c) Indigenous or Folk Medicine

Indigenous or folk Medicine is the medicine that has emerged from traditional beliefs, norms and practices based on centuries-old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and are mostly called as people's health care culture, home remedies or folk remedies or tribal medicine and they are practiced in different regions in different manners basing on the geographical conditions and cultural beliefs of the region.

II.2. Interplay of National Identities and Cultures

TM can also be in various forms. Some of the widespread traditional and complementary/alternative medicines are Ayurveda, Chinese Traditional Medicine, Osteopathy, Chiropractic, Homeopathy, Unani, Folk and Tribal Medicine and other Indian Systems of medicines (WHO 2001:1). The following is a brief analysis of the famous traditional systems of medicine which have close link with their national identities, lifestyles and cultures.

a) Traditional Chinese Medicine

The Traditional Chinese Medicine (TCM), which is the quintessence of the Chinese cultural heritage,[5] has a long history of 5000 years as that of the Chinese nation and has made an everlasting contribution to the Chinese Nation survival and prosperity. As an independent medical system, TCM is composed of not only medicine and treatment, but also a living philosophy (Liu 2003:197). Diagnosis and treatment are based on a holistic view of the patient and the patient's symptoms, expressed in terms of the balance of Yin and Yang. Yin represents the earth, cold, and femininity. Yang represents the sky, heat, and masculinity. The actions of Yin and Yang influence the interactions of the five elements composing the universe: metal, wood, water, fire, and earth. Practitioners of Chinese traditional medicine seek to control the levels of yin and yang through 12 meridians, which bring energy to the body. TCM can be used for promoting health as well as preventing and curing diseases. TCM encompasses a range of practices,

[5] TCM is also considered as one of the "precious jewels' of Chinese knowledge systems (Liu 2003:197).

including acupuncture, moxibustion, Chinese herbal medicines, manual therapies, exercises, breathing techniques, and diets. Surgery is rarely used in TCM (WHO 2001:2).

TCM, particularly Acupuncture, is the most widely used traditional medicine. It is practiced in every region of the world. Having its origin in China, it is now used in at least 78 countries and practised not only by acupuncturists, but also by allopathic practitioners (WHO-TMS 2002:12). [In China], a country where most of the population is not covered by the public healthcare system and cannot afford to go to hospital, there is also a tenfold increase in money for the TCM-related part of the public healthcare system to 8.5 billion Yuan. "Chinese medicine, which has served the Chinese people since antiquity, still has an important role in today's healthcare, especially in areas where people do not have access to, or could not afford for the treatments based on Western medicine," says Yu Wen-ming, deputy director of State Administration of Traditional Chinese Medicine (SATCM).[6]

The Government of China has paid significant attention to the development of TCM since the founding of the Peoples Republic of China in 1949. TCM is now protected by the Constitution of China wherein article 21 stipulates that "both modern medicine and traditional Chinese medicine must be developed".[7] Patenting of "modernized"[8] TCM is also allowed for a patent protection according to the Patent law of China, provided that it meets the requirements of patentability i.e. novelty, inventiveness and practical applicability.

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[6] As quoted in Qui, Jane (2007: 590), emphasis added.

[7] This was the first time in the world that the promotion and development of TM has been included in a national constitution. Recently, China has also announced an ambitious attempt to bring the ancient practice of TCM into line with modern standards. The government says it will expand basic and clinical research, and improve the testing and developing of TCM remedies for export. But critics question whether the research will meet the scientific standards necessary for international recognition (Qui 2007:591).

[8] Since 1950's, research and clinical practices of TCM have adopted many new theories and techniques by applying the modern chemistry, biology and pathology. "Modernization of TCM" is generally referred to the process of applying new techniques such as biochemistry to TCM for its separation and purification by isolating the active molecules for target diseases, and molecular pathology for building up of pathological models. For a clear understanding of the patenting procedure of the TCM in China, see generally, Liu (2003).

b) Chiropractic Medicine

Chiropractic Medicine was founded at the end of the 19th century by Daniel David Palmer, a magnetic therapist practicing in Iowa, USA. Chiropractic is based on an association between the spine and the nervous system and on the self-healing properties of the human body. It is practiced in every region of the world. Especially it is widely used in North American regions (Ong 2005:52). Chiropractic training programs are recognized by the World Federation of Chiropractic if they adopt international standards of education and require a minimum of four years of full-time university-level education following entrance requirements (WHO 2001:3).

c) Osteopathy

Osteopathy[9] is a type of alternative medicine which emphasizes the role of the musculoskeletal system in health and disease. It is also known as osteopathic medicine which uses treatments such as medication and surgery. In most of the developed countries it is a form of complementary medicine. Osteopathy emphasizes a holistic approach and the skilled use of a range of manual and physical therapies (Osteopathic Manipulative Medicine, or OMM in the United States) in the prevention and treatment of disease, particularly, but not solely, joint, muscle and nerve problems, such as back, neck and head pain. Osteopathic Physicians often see their role as facilitating the body's own recuperative powers by treating musculoskeletal or somatic dysfunction. The practice of osteopathic medicine began in the United States in 1874. Osteopathic medicine (formerly known as osteopathy) is "a complete system of medical care with a philosophy that combines the needs of the patient with current practice of medicine, surgery and obstetrics. The emphasis is on the interrelationship between structure and function, and has an appreciation of the body's ability to heal itself". It is also practiced in the countries like United Kingdom, Australia, Canada, New Zealand and India.

d) Tibetan Medicine

Tibetan Medicine is believed to be synthesized by considering various medical systems. The knowledge is noticed to be evolved in between 7th and 8th century BC. Medicine systems from China, India and Persia have influenced the ancient Tibetan

[9] The term "osteopathy" was coined by Andrew Taylor Still, M.D., an allopathically-trained physician who was born in 1828 in Virginia (source: www.healthlibrary.com/reading.cure.chapt.4.html).

medical practitioners to develop their own system of medicine much prior to the entry of the Buddhism into the Tibet. In the 11th century, this knowledge was codified into a unique system containing a synthesis of the principles of physical and psychological medicine imbued with a Buddhist spiritual understanding. This understanding formed a foundation for Tibetan medicine and benefited patients and doctors alike. It acknowledged how health and illness resulted both from the relationship between the mind and the body and people's connectedness to the natural world and sense of spirituality. Tibetan Medicine is widely practiced in the United States. In 1993 Dr. David Eisenberg of Harvard University created front-page news with an article in the New England Journal of Medicine documenting the extent to which people are paying out of pocket for so-called alternative or unconventional medical care. The growing awareness of increased market share in this area has lead to an explosion of interest from doctors, researchers, the government and industry (Tokar 1999).

e) Indian Systems of Medicine

Indian Systems of Medicine (ISM) are mainly referred to Ayurveda, Yoga, Unani, Sidha and Homeopathy.[10] The following is a brief description of the philosophy, evolution and practice of the ISMs in India.

i) Ayurveda

Ayurveda is believed to have originated in the 10th century BC, but its current form took shape between the 5th century BC and the 5th century AD. In Sanskrit, *ayurveda* means "science of life". Ayurvedic philosophy is attached to sacred texts, the Vedas, and is based on the theory of *Panchmahabhutas* — all objects and living bodies are composed of the five basic elements: earth, water, fire, air, and sky. Similarly, there is a fundamental harmony between the environment and individuals, which is perceived as a macrocosm and microcosm relationship. Ayurveda[11] is mostly considered as a branch of *Atharva Veda*,[12] which is treated as a repository of and treatise, on the knowledge and

[10] TMs like Chinese Traditional Medicine and Tibetan Medicine are also practiced in India but are not officially recognized by the Government of India.

[11] The term *Ayurveda* consists of two words, namely, 'Ayus' and 'veda' which means "the science of life". It is traditionally considered as a supplement to the Vedas. See generally, Sharma et al (1976) and Kutumbaiah (1962).

[12] In the Science of Medicine - Ayurveda, as in all other branches of study, the ancient Aryans claim to have derived this knowledge from the gods through direct relevation. The *Brihat-trayi* books- Sushruta

wisdom of great sages and seers, acquired, tested and handed down to succeeding generations. Life in Ayurveda is conceived as the union of body, senses, mind and soul. The living man is a conglomeration of three humours (*Vata, Pitta* and *Kapha*), seven basic tissues (*Rasa, Rakta, Mansa, Meda, Asthi, Majja* and *Shukra*) and the waste products of the body such as faeces, urine and sweat. Ayurveda deals elaborately with measures for healthful living during the entire span of life and its various phases. Besides, dealing with principles for maintenance of health, it has also developed a wide range of therapeutic measures to combat illness. These principles of positive health and therapeutic measures relate to physical, mental, social and spiritual welfare of human beings. Ayurvedic medicine includes herbal medicines and medicinal baths. It is widely practised in South Asia, especially in Bangladesh, India, Nepal, Pakistan, and Sri Lanka (GOI 1998-99). Ayurveda is not only a well-documented system of medicine, but also represents a way of healthy living. The famous texts of Ayurveda- *Charaka Samhita* and *Shushrut Samhita* which are considered as the oldest texts of Ayurveda were taught in the ancient universities of *Takshashila* and *Nalanda. Ayurveda* is considered as one of the oldest systems of health care in India dealing with both the preventive and curative aspects of life in a most comprehensive way and presents a close similarity to the WHO's concept of health propounded in the modern era.[13]

Samhita, Charaka Samhita, and Ashtanga Sangraha - represent the systemization of the medical science of Ayurveda upto the fifth century AD. *Charaka Samhita* (as preached by Agnivesha and compiled by Charaka), written in the first century AD, is considered as the first scientific medical text in India. While it does list 1500 plants with description, a mere 350 are pronounced medicinal. *Charaka* as a physician was interested in the diagnostic and prescriptive aspects of healing. Four hundred years later, Sushruta wrote his Sushruta Samhita, a text on the practice of surgery. Known as the father of surgery, Sushruta details the 125 surgical instruments used by him, as also the highly intricate surgeries associated with caesarean sections, plastic surgery and the setting of compound fractures. It is his techniques, particularly in the creation of the new nose, that have made Sushruta world-renowned. Both Caraka and *Shushrutha* in their *treatises* described the origin of Ayurveda, as disclosed by the holy saint and a king of Varanasi, Dhanwantari to his disciple Shushruta. Ayurveda is treated as an Upanga (subdivision) of the *Atharvana Veda*, while according to others, the science of the Ayurveda has its origin in the verses of the Rik Samhita. The Ashtanga Sangraha by Vagbhata is third of the great texts. Written in the seventh century AD, it discusses the eight branches of Ayurveda: Salya tantra (major surgery), Salakya tantra (minor surgery), Kaya cikitsa, (therapeutics), Bhuta vidya (demonology), Kaumara bhrtya (paediatrics), Agada tantra (toxicology), Rasayana (elixirs), Vaji karana (aphrodisiacs). All these eight branches deal with the prevention and cure of deceases and morbid conditions in their respective specialized fields (Bishagaratna 1963:1).
For more details on the evolution and practice of Ayurveda, see also, Jaggi (1999); Kutumbaiah (1962); Leslie (1976); Reddy (eds.) (1966); Sharma (1991); and Kumar (1998).

[13] About 30 years back, WHO adopted Traditional Medicine Programme in conjunction with the goal of "health for all" in its adoption of primary health care approach. WHO endorses only that therapy which has solid scientific evidence with no toxicity. In view of this Ayurveda is duly recognised by the WHO.

In India, development and growth of Ayurveda, the science of life, was coextensive with the growth and evolution of Indian civilization and culture. Vedas, which are considered to be the repositories of the recorded Indian culture, have mention of this knowledge both in theoretical and practical form (Sharma 1991:2). In other ancient works there was a mention of such current medical subject like anatomy, physiology, etiology, pathology, treatment and environmental factors. It is generally believed that Ayurveda has played a vital role in the development of Indian culture that it has been documented in an integrated form in the Vedas. It is argued by P.V. Sharma that, "...when Vedas became target of attacks from many corners, Ayurveda was utilized as powerful instrument for supporting the authoritativeness of the Vedas (Sharma 1991:2).

According to a WHO report, Ayurveda is extensively practiced in the South Asian countries and considerably used in the US for the daily health care needs (Ong 2005:47). However, it is not recognized in many parts of the world except by the South Asian countries wherein it is included in the national health policies of these countries (Ong 2005:17, 33).[14]

ii) Unani

Unani is one of the oldest systems of medicine in the world which is still popular and practiced in Indian sub continent and other parts of the world with different names.[15]

Later on the policy of the WHO regarding traditional medicine was presented in the Director- General's report on Traditional Medicine and Modern Health Care to the Forty-fourth World Health Assembly 1991, which stated that "WHO collaborated with its Member States in the review of national policies, legislation and decisions on the nature and extent of the use of traditional medicine in their health systems" (WHO/TRM/98.1:2).

[14] However, it is noticed that, in the recent times funding of the research and development of the Ayurvedic medicine in the western countries is also considerably increasing. Especially the annual funding of the CAM including Ayurveda has been significantly increased from 49.9 per cent to 68.3 percent in the year 2000. It is expected to increase even more in the coming years (WHO-TMS 2002:18).

[15] Unani system is a science which deals with the preventive and promotive aspects of human being and health problems occurred by the ecological and environmental factors, which may vitiate humors i.e. Blood, Phlegm, Yellow bile and Black bile, the fluids circulating in the body vessels. It teaches to maintain the health and treat if affected by disease by bringing back the balance in imbalance humors. Humors are one of the basic principles & concepts conceptualized by the 'Father of Medicine', 'Hipporcrates'. In the basic principles and concepts the human body is considered to be made up of the following components: Arkan (Elements); Mizaj (Temperament); Akhlat (Humors); Aza (Organs); Arwah (Spirit); Quwa (Powers); Afa'l (Function). Unani Medicine is known in different parts of the

The theoretical framework of the Unani medicine is based on the teachings of Hippocrates (460-377 BC).[16] After Hippocrates, a number of other Greek scholars enriched the system considerably.[17] Galen (131–210 AD), Rhazes (850–925 AD), and Avicenna (980–1037 AD) heavily influenced Unani's foundation and formed its structure. Unani medicine in India was introduced in 1351AD by Arabs[18]. Unani theory is based on the four bodily humours: blood, phlegm, yellow bile, and black bile. According to Basic Principals of Unani the body is made up of the four Basic elements i.e. Earth, Air, Water, Fire which have different Temperaments i.e. Cold, Hot, Wet, Dry. After mixing and interaction of four elements a new compound having new temperament comes into existence i.e. Hot Wet, Hot Dry, Cold Wet, and Cold Dry. The body has the Simple and Compound Organs which got their nourishment through four Humours. Health is a state of Body in which there is equilibrium in the humours and functions of the body are normal in accordance to its own temperament and the environment. When the equilibrium of the Humours is disturbed and functions of the body are abnormal, in accordance to its own temperament and environment, that state is called Disease. Unani medicine believes in promotion of health, prevention of diseases and cure. Unani draws from the traditional systems of medicine of China, Egypt, India, Iraq, Persia, and the Syrian Arab Republic (GOI, 1997).

iii) Siddha

Siddha[19] system is also one of the oldest systems of medicine in India. It is largely therapeutic in nature. The system has developed a rich and unique treasure of

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world, with different names such as Greco-Arab Medicine, Ionian Medicine., Arab Medicine, Islamic Medicine, Traditional Medicine and Oriental Medicine etc

[16] He was the first Unani Physician who opened the education of Medicine to all communities, so he is also known as the "Father of Medicine" in Allopathic also because modern medical science was developed on the foundation of Hippocratic philosophy of health and disease.

[17] Among them, Galen (131-210 AD) stands out as the one who stabilized its foundation, on which Arab and Persian physicians like Thazes (850 - 925 AD) and Avicenna (980 - 1037 AD) constructed an imposing edifice.

[18] The first institution of Unani medicine in India was established in 1872 as Oriental College at Lahore.

[19] According to the literature available, the term Siddha means "achievements" and Siddhars were saintly persons who achieved results in medicine. Eighteen Siddhars were said to have contributed towards the development of this medical system. It is believed that it was Shiva who unfolded the knowledge of Siddha system of medicine to his concert Parvati who handed it down to Nandi Deva and he to the Siddhars. The Siddhars were great scientists in ancient times. According to tradition, the origin of Siddha system of medicine is attributed to the great Siddha Ayastiyar. Some of his works are still

drug knowledge in which use of metals and minerals is very much advocated. According to a traditional belief, the origin of Siddha system of medicine is attributed to the great Siddha Ayastiyar. Some of his works are still standard books of medicine and surgery in daily use among the Siddha medical practitioners. Principles and doctrines of this system, both fundamental and applied, have a close similarity to Ayurveda, with specialization in Iatro-chemistry. According to this system, the human body is the replica of the universe and so are the food and drugs irrespective of their origin. Like Ayurveda, this system believes that all objects in the universe including human body are composed of five basic elements namely, earth, water, fire, air and sky. The food, which the human body takes and the drugs it uses are all, made of these five elements. The proportion of the elements present in the drugs vary and their preponderance or otherwise is responsible for certain actions and therapeutic results. As in Ayurveda, this system also considers the human body as a conglomeration of three humours, seven basic tissues and the waste products of the body such as faeces, urine and sweat. The food is considered to be basic building material of human body which gets processed into humours, body tissues and waste products. The equilibrium of humours is considered as health and its disturbance or imbalance leads to disease or sickness. This system also deals with the concept of salvation in life. The exponents of this system consider achievement of this state is possible by medicines and meditation. It is also believed that this system is effective in treating chronic cases of liver, skin diseases especially 'Psoriasis', rheumatic problems, anemia, prostate enlargement, bleeding piles and peptic ulcer. The Siddha medicines which contain mercury, silver, arsenic, lead and sulphur have been found to be effective in treating certain infectious diseases including venereal diseases. The literature of Siddha medicine is in Tamil and is practiced largely in Tamil speaking part of India and abroad. Though there is no clear evidence of the origin of Siddha medicine, it is generally considered that Siddha was practiced in the southern part and Ayurveda was prevalent in the northern part of India right from the day of the development of the human civilizations in these parts of the world. Practitioners have claimed that Siddha medicines are effective in reducing the highly debilitating problems that manifest themselves among

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standard books of medicine and surgery in daily use among the Siddha Medical practitioners. Source of the history. is the website of the AYUSH, Ministry of Health and Family Welfare, Government of India. URL: http://indianmedicine.nic.in/html/siddha/siddha.htm

patients of HIV/AIDS. More research into the efficacy of these medicines is presently in progress (AYUSH Website).

iv) Yoga

Yoga is a science as well an art of healthy living physically, mentally, morally and spiritually. Yoga has its origin in the Vedas, the oldest record of Indian culture. It was systematized by the great Indian sage Pathanjali through a special *Darshana* and compiled and refined various aspects of Yoga in his treatise "Yoga Sutras" (aphorisms).[20] Yoga philosophy is described as an Art and Science of living in tune with *Brahmand* - the Universe. Many different interpretations of the word Yoga have been handed down over the centuries. One of the classic definitions of Yoga is "to be one with divine".[21] It is understood that, Yoga is not a religion and that it is a philosophy of life based on certain psychological facts and it aims at the development of a perfect balance between the body and the mind that permits union with the divine i.e. perfect harmony between the individual and the cosmos.

v) Naturopathy

Naturopathy is a system of healing science stimulating the body's inherent power to regain health with the help of five great elements of nature – Earth, Water, Air, Fire and Ether. Naturopathy is treated as a call to "Return to Nature" and to resort to simple way of living in harmony with the self, society and environment.[22] The whole practice of Nature cure is based on the following three principles: a) Accumulation of morbid matter; b) abnormal composition of blood and lymph; and c) Lowered vitality. Nature Cure believes that all the diseases arise due to accumulation of morbid matter in the body and

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[20] Through these yoga sutras, Pathanjali advocated the eight fold path of Yoga, popularly known as "Ashtanga Yoga" for all-round development of human personality. They are – Yama, Niyama, Asana, Pranayama, Pratyahara, Dharana, Dhyana & Samadhi. These eight limbs are considered to be perfectly designed that there is absolutely no scope for any addition or alteration since these are formulated on the basis of multifarious psychological understanding of human personality.

[21] Swami Vivekananda defines Yoga as "a means of compressing one's evolution into a single life or a few months or even a few hours of one's bodily existence". By Sri Aurobindo, Yoga meant a methodological effort towards self perfection by the development of potentialities latent in the individual.

[22] Nature Cure movement started in Germany and other Western countries with "Water Cure" (Hydrotherapy). Water Cure was synonymous with Nature Cure in those early days.[22] Nature Cure movement gained momentum in India as Mahatma Gandhi, "Father of the Nation" became much interested in this system and included it in his programmes. He has also established a Nature Cure Hospital in Uruli Kanchan, Distt. Poona, Maharashtra which is still functioning.

if scope is given for its removal, it provides cure or relief. It also believes that the human body possesses inherent self constructing and self healing powers.

The fundamental difference in Nature Cure with other systems is that its theory and practice are based on holistic view point whereas the latter's approach is specific. Nature Cure does not believe in the specific cause of disease and its specific treatment but takes into account the totality of factors responsible for diseases such as one's un-natural habits in living, thinking, working, sleeping, relaxation, sexual indulgence etc, and also considers the environmental factors involved which on the whole disturbs the normal functioning of the body and lead it to a morbid, weak and toxic state. For treatment it primarily stresses on correcting all the factors involved and allowing the body to recover itself. A Nature Cure physician helps in Nature's effort to overcome disease by applying correct natural modalities and controlling the natural forces to work within safe limits. The five main modalities of treatment are air, water, heat, mud and space. In the recent times these systems are emerging as the effective methods and means to improve the total personality and to build a healthy society. These systems have been adopted as a way of life rather than a mode of treatment.[23]

iv) Homeopathy

Homoeopathy,[24] although has originated in Germany and came to India in the early 18th century[25] has been completely assimilated, accepted and enriched in India like

[23] For instance, in the recent years it was observed that there is a growing awareness among the people about the efficacy and utility of Yoga and Nature Cure in keeping one fit at physical, mental, emotional, social and spiritual planes. Though the basic Nature Cure deals only with *Pancha Mahabhoota's*, the recent developments advocates the practice of drugless therapies like Massage, Electrotherapy, Physiotherapy, Acupuncture and Acupressure, Magnetotherapy etc., and above all, diet plays a major role (CCRY Website).

[24] The word 'Homoeopathy' is derived from two Greek words, *Homois* meaning similar and *pathos* meaning suffering. Homoeopathy simply means treating diseases with remedies, prescribed in minute doses, which are capable of producing symptoms similar to the disease when taken by healthy people. Dr. Samuel Hahnemann (1755-1843) gave it a scientific basis in the early 19th century. It has been serving suffering humanity for over two centuries and has withstood the upheavals of time and has emerged as a time-tested therapy. It is considered that the principle of Homoeopathy has been known since the time of *Hippocrates* from Greece, around 450 BC. More than a thousand years later the Swiss alchemist *Paracelsus* employed the same system of healing based upon the principle that "like cures like". But it was not until the late 18th century that Homoeopathy as it is practiced today was evolved by the great German physician, Dr. Samuel Hahnemann. He was appalled by the medical practices of that time and set about to develop a method of healing which would be safe, gentle, and effective. He believed that human beings have a capacity for healing themselves and that the symptoms of disease

any other ISMs. The key point of Homoeopathy is that it does not treat disease per se. It is based on the Principle "*Similia Similibus Curentur*" which means, "*let likes be treated by likes*".

Homeopathy was first mentioned by Hippocrates (462–377 BC), but it was a German physician, Hahnemann (1755–1843), who established homeopathy's basic principles: law of similarity, direction of cure, principle of single remedy, the theory of minimum diluted dose, and the theory of chronic disease. In homeopathy, diseases are treated with remedies that in a healthy person would produce symptoms similar to those of a disease. Rather than fighting the disease directly, medicines are intended to stimulate the body to fight the disease. Its strength lies in its evident effectiveness as it takes a holistic approach towards the sick individual through promotion of inner balance at mental, emotional, spiritual and physical levels.

It is more than a century and a half now that Homoeopathy is being practiced in India. It has blended so well into the roots and traditions of the country that it has been recognised as one of the National Systems of Medicine and plays an important role in providing health care to a large number of people. By the later half of the 19th century, homeopathy was practiced throughout Europe as well as in Asia and North America. Homeopathy has been integrated into the national health care systems of many countries, including India, Mexico, Pakistan, Sri Lanka, and the United Kingdom (WHO 2001). A rough study indicates that about 10% of the Indian population solely depends on Homoeopathy for their Health care needs (AYUSH).

II.3. Some basic Issues Relating to Traditional Medicine

a) What is 'Traditional' about Traditional Medicine?

After analyzing various forms of TM we need to address nature of TM and TK as to whether it should be termed as 'ancient' or 'contemporary'. In this context there are

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reflect the individuals struggle to overcome his illness. For more details visit URL: http://indianmedicine.nic.in/html/homoeopathy/homoe.htm#intro

[25] Homoeopathy entered India in 1839 when Dr. John Martin Honigberger was called to treat Maharaja Ranjit Singh, the ruler of Punjab, for paralysis of vocal cords and oedema. This royal patronage helped the system to have its roots in India. A large number of missionaries, amateurs in Indian civil and military service personals practiced Homoeopathy extensively and spread this system mostly in Bengal and South India (Jaggi 2000:33).

contrasting opinions. Some say TK is old and is generally passed from generations to generation, whereas others hold the view that it is "traditional" only to the extent that its creation and use are part of the cultural traditions of communities.[26] According to some scholars TM is not a static body of knowledge because it continues to evolve with the practices of the individuals or communities that hold and use it (Correa 2001a). It can be created every day as a response of the individuals and communities to the challenges posed by their social ad natural environment (WIPO/IPTK/MCT/02/INF.4). As it is opined by Richard Wilder (2001), the term "traditional", does not necessarily mean that the knowledge is ancient-although the antiquity of some traditional knowledge makes its protection problematic. What is "traditional" about the TM is the way it acquired, used and transmitted. It does not necessarily mean that it is old (Wilder 2001:10).[27] The Canadian Indigenous people's organization, the Four Directions Council, for example sums up this debate aptly where it states,

> What is "traditional" about traditional [medical] knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is unique to each indigenous culture, lies at the very heart of its "traditionality". Much of this knowledge is actually quite new, but it has a social meaning and legal character, entirely unlike the knowledge indigenous people acquire from settlers and industrialized societies.[28]

b) Who Owns Traditional Medicine?

The other basic question regarding TM is its 'possession'. In the ancient India, the knowledge of medicine was held as a close preserve in a few families of hereditary physicians popularly called as *"Vaidyas"*. But now the same knowledge can be held either by a community of people who are descendants of the earlier *vaidya* families or others. Situations like these often pose a question as to who owns TM - Whether it is possessed by individuals or by a group of people, or a family or by a community- which is highly debated for the purpose of its protection and sharing of benefits. However this question can be clarified to some extent by the literature on the subject wherein TM

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[26] The former view is expressed by the authors like Mugabe (1998) and the latter view is expressed by Liu (2003), Correa (2001), (2001a), Dutfield (2000), etc.

[27] On this point also see, Heath and Weidlich (2003); Liu (2003).

[28] As quoted in (WIPO/IPTK/MCT/02/INF.4).

categorized into three types based on its possession:[29] i) Individual Knowledge, ii) Distributed Knowledge and iii) Communal Knowledge.

i) Individual knowledge

In some cases, individuals produce traditional medical knowledge without any interface with the community or outsiders. In such cases, the knowledge is held by individuals (individual knowledge). For instance, some individual traditional healers continuously improve or innovate on existing body of knowledge through sustained observation and experimentation.

ii) Distributed Knowledge

In other cases knowledge is in the possession of some but not all members of a group (distributed knowledge). In such cases, the knowledge is asymmetrically distributed among individuals within a group, even though such individuals may not be aware that others in and outside the community share the same knowledge. "Individual" and "distributed" knowledge are often interconnected and sometimes healers compare notes and share remedies across quite wide geographic areas.

iii) Communal Knowledge:

Certain medical knowledge may be available to virtually all members of a group (communal knowledge). In such a case, the knowledge is freely available to its members although it may concentrate among the old members of the society. The community knowledge can also be understood as the knowledge in public domain.[30]

However, one can say that though a system of medicine is owned by a community, the individual components of that particular system of medicine might have been developed by certain individuals of the group. So also a knowledge originally prepared by an individual, later shared by a community may be modified by applying new technologies or methods according to the requirements, can also be considered as a new knowledge in itself. For instance, a study on herbal knowledge in India has concluded that:

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[29] The authors like Richard Wilder (2001) and Kibet A. Ng'etich (undated) categorizes the traditional and alternative medicines into above three categories.

[30] Ng'tech (undated) states that Distributive knowledge is some times also referred as individual knowledge as well.

> There is no clear demarcation between what belongs to the general community, specific community, or individuals within the communities. Certainly for the herbalists, as indicated in the results of the case study, herbal knowledge is treated as personal property. However, some of the knowledge they possess is relatively available in the same form in the general community due to the older tradition of sharing knowledge. The herbalists have continuously innovated what is available in the general community and hence they possess special rights to their innovations. It is hard to determine how the benefits should be shared if there is no clarity in the ownership (Sharma 2000:5).

In cases where there is distributed and common possession of knowledge, complex issues of entitlement to any possible IPR also arise. Since the Western IPR systems do not provide for the granting of rights to communities as such (Correa 2001a), the legal dimensions of the problem needs consideration. In many instances, in addition, the same knowledge may be held by more than one community, and an issue of geographical or historical priority arises (for instance, kava in various Pacific Cultures, and the use of neem derivatives throughout South and South East Asia). The multiplicity of factual situations as to the possession of TM makes it particularly hard to apply existing IPRs.

c) Codified or Uncodified Status of TM

Traditional medicine may be reduced to writing (codified) or transmitted orally (non-codified). Systems of TM codified in writing are often considered as sophisticated systems of medicine supported by theories and rich experience. Such TM is often widely diffused on a national scale as well as beyond national borders, as in the case, for example, of Traditional Chinese Medicine (TCM), Ayurveda, Unani, Tibetan, Mongolian and Thai traditional medicine, Kampo and Korean traditional medicine (based on TCM) (Correa 2001a). In India, for example, there are both codified and oral systems of TM.

i) Folk Stream or Non-codified Traditional Medicine[31]

This stream comprises mostly the oral traditions practiced by the rural villages. The carriers of these traditions are millions of housewives, thousands of traditional birth attendants, bone setters, village practitioners skilled in acupressure, eye treatments, treatment of snake bites and the traditional village physicians/herbal healers, the

[31] Folk medicine is also referred as Indigenous medicine. In India it is mostly referred as Tribal Medicine.

"vaidyas" or the tribal physicians. These streams of inherited traditions are together known as Local Health Traditions (LHT).

ii) Classical Stream or Codified Traditional Medicine

The second level of traditional health care system is the scientific or classical systems of medicine. This comprises of the codified and organized medicinal wisdom with sophisticated theoretical foundations and philosophical explanations expressed in classical texts like 'Charka Samhita', 'Sushruta samhita', 'Bhela samhita', and hundreds of other treatises including some in the regional languages covering treaties of all branches of medicine and surgery. Systems like Ayurveda, Siddha, Unani, Amchi and Tibetan, etc. are expressions of the same. Ayurveda was taught in the ancient universities in India and evolved, developed and flourished mostly among the urban centres and thus used to be a refined system of medicine[32] (Tiwari Report, GOI 1997).

However, there are many other traditional medical systems or practices which are not codified but still in practice in the form of indigenous or folk medicine. These are just orally transmitted from generation to generation since time immemorial. Non-codified, orally transmitted knowledge is generally held and used only within a limited circle of people such as within specific indigenous or rural communities and falls within the sometimes used terms 'indigenous' (tribal), 'farmers' (rural), 'popular' (folk) knowledge (Koning, 1998:263). There are statistics which reveal that around 80 per cent of the rural populations of the developing countries depend upon these indigenous medicines because of many cultural and economic reasons (Heath and Sabine 2003:70).

d) Does the Traditional Medicine Relate to Products or Processes?

TM involves use of natural products and processes such as diagnosis and treatment, including physical, mental and spiritual therapies. The application of such methods is strongly influenced by the culture and beliefs dominant in a particular community, to the extent that they may be ineffective when applied in a different context. TM may include these two aspects, practiced alone or in combination. For example, in

[32] The codified knowledge systems of TM include the Ayurvedic system of medicine, which is codified in the 54 authoritative books of the Ayurvedic System, the Sidha System, codified in 29 authoritative books, and the Unani Tibb traditional medicine is codified in 13 authoritative which are recognized by the Government of India in the First Schedule of the Drugs and Cosmetics Act, No. 23 of 1940, as amended by the Drugs and Cosmetics (Amendment) Act no.71 of 1986.

India most of the traditional medicines are practiced by performing rituals and chanting mantras/hymns while administering medicine to the patient. The traditional medical practitioners of India often express a view that without performing certain rituals, the medicine may not have the intended effect in curing the ailments of the patient. Therefore, one can say that, TM may be a product or process or a combination of both depending upon the traditional and cultural beliefs of the traditional medical practitioners of a particular geographical area.

Products used in the various traditional medical practices include plants or parts of plants, animals or parts of animals and minerals and are commonly known as "Herbal Products". These herbal products are mostly the extracts of the herbal preparations which are produced by subjecting herbal materials to extraction, fractionation, purification, concentration, or other physical or biological processes. Herbal products may contain excipients, or inert ingredients, in addition to the active ingredients. They are generally produced in larger quantities for the purpose of retail sale. In India, for instance, the codified systems of medicine utilize about 2000 plant species for medicinal purpose, while the tribal communities, who live in and around the forests, utilize over 8000 species of plants, most of which are otherwise not known to the outside world (Pushpangadan 2002:5). Examples of traditional medical processes include acupuncture and related techniques, manual therapies, qigong, tai ji, yoga, naturopathy, thermal therapy, aroma therapy (where a medicine is not administered to the patient) and other physical, mental, spiritual and mind-body therapies. These are usually called as non-drug therapies.[33]

II.4. Conclusion

TM is a multifaceted concept. Based on the above description of the nature and scope of the TM, one can say that there are four aspects of traditional medicine that should be considered in connection with question of its protection. TM may be both ancient and contemporary and it could exist in both codified and non-codified forms. It may involve products, processes, rituals and philosophical preaching and may be owned

[33] For a detailed study on various traditional medicinal practices practiced worldwide, see WHO (2001).

by individuals or a group of people or even sometimes ownership cannot be determined. Therefore, each system of TM differs from other depending upon its nature and components. At this stage it is necessary to clarify the definition of TM and TK. The same is dealt in the next chapter.

CHAPTER III

CHAPTER III

PROTECTING TRADITIONAL MEDICINE: EMERGING LEGAL ISSUES

III.1. Introduction

Traditional knowledge is a broad term which could inter alia, include "traditional knowledge, innovations and practices", "heritage of indigenous peoples" and "indigenous heritage rights", "traditional medical knowledge", "expression of folklore" or "traditional and popular culture", "intangible cultural heritage", "indigenous cultural and intellectual property", "traditional ecological knowledge" and "traditional and local technology, knowledge, know-how and practices" (WIPO/GRTKF/IG/3/9). Whilst a number of definitions for TK have been put forward, none of them could capture its essence. However, it could be understood as, "the body of knowledge built by a group of people through generations living in close contact with nature[1] or tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields which have generally been transmitted from generation to generation, sometimes written and sometimes in oral form[2] pertaining to a particular people or its territory and, are constantly evolving in response to a changing environment[3] that is vital

[1] The Conference of Parties to the Convention on Biological Diversity, 2002 has defined the term TK as: "traditional knowledge ... is a term used to describe a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use..." (UNEP/CBD/TKBD/1/2, paragraph 85).

[2] Philippines in its Community Intellectual Property Rights Act, 1997 defines TK or traditional methods as, "discoveries, innovations and technologies made by indigenous peoples and local communities that are usually not recorded in written form, and are transmitted orally from generation to generation. Indigenous knowledge forms part of traditional knowledge, and refers to knowledge distinct to indigenous peoples [Section 3(n)].

[3] The Secretariat of the World Intellectual Property Organization (WIPO) has defined the term Traditional Knowledge as follows: "Traditional knowledge... refer[s] to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. "Tradition-based" refers to knowledge systems, creations, innovations and cultural expressions which have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medical knowledge, including related medicines and remedies; biodiversity-related knowledge; "expressions of folklore" in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of TK would be items not resulting from intellectual activity in the

for conservation and sustainable use of biological resources which is of socio-economic value[4] and not limited to any specific technical field, and may include agricultural, environmental, healthcare and medical knowledge, knowledge associated with genetic resources or other components of biological diversity, and know-how of traditional architecture and construction technologies".[5]

In the context of IP Protection, TK is characterized as the knowledge which is generated, preserved and transmitted in a traditional context, distinctively associated with the traditional or indigenous culture or a community which preserves and transmits it between generations and linked to a local or indigenous community through a sense of custodianship, guardianship or cultural responsibility such as a sense of obligation to preserve the knowledge or a sense that - permitting misappropriation or demeaning usage would be harmful or offensive which may be expressed formally or informally by customary law or practices. 'knowledge' in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological context, and identified by the source community as being TK (WIPO/GRTKF/IC/6/4, paragraph 58).

III.2. Traditional Medicine: Terminological Issues

Traditional medicine just as traditional knowledge is yet to be defined in acceptable terms. TM is described as manifestations of many cultures that have given rise to it. Given this diverse nature of TM, it is also highly problematic to confine to single definition of the term TM. The comprehensiveness of the term 'traditional medicine' and the wide range of practices it encompasses make it difficult to define or describe,

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industrial, scientific, literary or artistic fields, such as human remains, languages in general, and other similar elements or "heritage" in the broad sense" (WIPO/GRTKF/IC/3/9).

[4] The Organization of African Union Model Legislation for the Protection of the Rights of Local Communities, farmers, breeders and Access, 2000 (OAU Model) for the Regulation of Access to Biological Resources defines "Community Knowledge" or "indigenous knowledge" as "the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities.

[5] The South Asian Countries define TK as "the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional systems, and knowledge that is embodied in the traditional lifestyles or a community or people, or is contained in codified knowledge systems passed between generations, such as Ayurveda, Unani, Siddha systems of health care. It is not limited to any specific technical field, and many include agricultural, environmental, healthcare and medical knowledge, knowledge associated with genetic resources or other components of biological diversity, and know-how of traditional architecture and construction technologies" (SAARC 2006).

especially in a global context. Many writers have expressed their view that it is always better to define TM in terms of its protection. At this stage, it is worth quoting the definition of TM by the WHO[6] which inter alia states:

> [TM is] the sum total of knowledge, skills, and practices based on the theories, beliefs, and experiences Indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement of treatment of physical and mental illness. The terms complementary/ alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries (WHO/EDM/TRM/2000).

TM is differently described by different states. Philippines defines TM in its Traditional and Alternative Medicine Act, 1997 of Philippines "as the sum total of knowledge, skills and practice on health care, not necessarily explicable in the context of modern, scientific philosophical framework, but recognized by the people to help maintain and improve their health towards the wholeness of their being the community and society, and their interrelations based on culture, history, heritage, and consciousness" whereas India characterizes TM as two social streams: Folk and classic. Folk is mainly referred to the medicine which is orally transmitted form generation to generation and Classic to the codified systems of traditional medicine, for instance, Ayurveda, Siddha, Unani, etc.

III.3. Distinguishing Traditional Medicine and Modern Medicine

TM differs from the Western medicine in its basic medical orientation, physiological theories, etiology, diagnostics, therapeutics and pharmacology. The major difference between TM and Western medicine is their fundamental difference in medical theories. While Western medicine adopts the Cartesian reductionism approach separating the body and the mind, TM is holistic. Allopathic practitioners emphasize the scientific approach of allopathic medicine, and contend that it is free of cultural values. TM therapies have developed rather differently, having been very much influenced by the culture and historical conditions within which they first evolved. Their common basis is a

[6] WHO has also offered the following conceptualization of traditional medicine: On the basis of a community's or a country's culture, history and beliefs, traditional medicine came into being long before the development and spread of western medicine that originated in Europe after the development of modern science and technology. The knowledge of traditional medicine is often passed on verbally from generation to generation. Nevertheless, in some cases a sophisticated theory and system is involved (WHO Geneva & Zhang 2001:iv).

holistic approach to life, equilibrium between the mind, body and their environment, and an emphasis on health rather than on disease. Generally, the provider focuses on the overall condition of the individual patient, rather than on the particular ailment or disease from which the patient is suffering (WHO/EDM/2002.4). TM is regarded as an art as well as a science. It exists not simply as medicine or therapy but also represents ancient philosophy of the regions where it is practiced, which describes how humans interact with the natural world. TM mainly focuses on health maintenance and, in the treatment of diseases, emphasizes the enhancement of the body's resistance to diseases.[7]

III.4. Protecting Traditional Medicine: Emerging Concerns

The growing importance attached to TK, and related concerns about preserving cultural and biological diversity, have raised policy, ethical and legal questions at the national, regional and international levels. TK arises as an issue in relating to food and agriculture, biological diversity and the environment, biotechnological innovation and regulation, human rights, cultural policies, and trade and economic development. The working concepts of TK in each forum tend to be shaped by the policy framework of that forum, leading to a decentralized and disintegrated set of approaches, in which the issues are subjected to differing policy considerations, cultural and ethical environments, analytical tools and legal concepts (WIPO/GRTKF/IC/3/9).

Several proposals have been made, within and outside the IPRs system, to 'protect' TK. Such proposals often fail to set out clearly the rationale for its protection (Correa 2001:5). Some understand "protection" in the context of IPRs, where it essentially means to exclude the unauthorized use by third parties of protected knowledge. Under this approach, IPRs may constitute either an "offensive mechanism"[8]

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[7] For a deeper discussion on various ISMs and their philosophy, see generally Kutumbaiah (1968); Reddy (1966); Jaggi (1993); and on the Chinese herbal medicine and how it is different from the western medicine see, Hsiao (1997).

[8] India is the main proponent of these "offensive" mechanisms for the protection of TK. In its submission made to the WTO on the implementing issue of the relationship between TRIPS and the CBD, India has stressed for the inclusion of the "Article 29*bis*" to the TRIPS Agreement. It has urged the Member states as follows:

> Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of

to support the commercialization of TK and to ensure benefit sharing,[9] or a "defensive tool" to prevent the misappropriation of traditional knowledge. Others regard "protection" as a 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. Protection here has a direct positive role in supporting TK based communities' livelihoods and cultures, and requires the application of mechanisms - such as conservation projects - where IPRs have little or no part to play (Correa 2001:5,6).

However, in a given case the question of protection arises only when there is a need for such protection. Protection could be in many ways. In what ways a particular object/thing has to be protected is directly linked to the question as to what sort of harm or damage is caused that has created a need for protection. An amount of compensation can be claimed only when there is a violation of a legal right. All these theoretical queries are very much relevant to be answered when one talks about the protection of TK and benefit sharing arrangements for the use of the traditional and biological resources of the traditional, indigenous and local communities.

Before considering how to protect TK, a basic question as to why do we need a protection regime at all? And what are those reasons compelling the international community especially the developing world to advocate for the protection of TK and biological resources. The present section of the chapter attempts to analyze the reasons and justifications as proposed through the mechanisms for the protection of TK and its subset TM.

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compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge (WT/GC/W/564, TN/C/W/41).

The other states which supported these propositions were: Brazil, Pakistan, Peru, Thailand and Tanzania. For a comment on the offensive and defensive mechanisms, see generally, Downes (1997).

[9] "Benefit sharing" refers here to the fair an equitable participation of TK holders in the benefits arising from the commercial and other utilization of TK [Article 15(7) of CBD].

a) Positive Protection[10]

One of the main reasons for the protection of TK is to preserve the knowledge systems of the traditional and indigenous communities whose basic livelihood forms these systems. For this countries have proposed the 'Offensive Mechanisms' or 'Positive Protection' which is often referred to the commercialization of the TK by providing access to the genetic resources after taking prior informed consent from the owners of the TK with a condition of compulsory sharing of the monitory benefits gained by the commercialization of TK. However the 'positive protection' also refers to the acquisition by the TK holders themselves of an IPR such as patent or an alternative right provided in a *sui generis* system (Dutfield 2006:22).[11] This principle is projected to be beneficiary especially for the countries where much of the TK is already in wide circulation but may still be subject to the claims of the original holders.

CBD is the main forum where this mechanism is extensively debated and resulted in the form of the Bonn Guidelines on Access and Benefit Sharing in the 6th meeting of the COP.[12] India is also one of the chief proponents of this mechanism. It has included the provisions relating to the access and benefit sharing in its Biological Diversity Act 2002.[13] Similar provisions were also adopted by Peru through a law passed in 2002, known as the Regime of Protection of the Collective Knowledge of Indigenous Peoples. Under this law, in case of use of public domain TK, an indigenous compensation may be entitled compensation from outside parties in the form of 0.5 per cent of the value of

[10] Positive protection is mainly advocated by the developing countries and has been adopted in the national legislations. For instance, Peru has adopted this approach through passing a law in 2002, known as the Regime of Protection of the Collective Knowledge of Indigenous Peoples. In the case of use of public domain traditional knowledge, an indigenous group may be entitled to compensation from outside parties in the form of 0.5 per cent of the value of sales of any product developed from the knowledge. The money is paid into the Fund for the Development of Indigenous peoples.

[11] Dutfield (2006) explains that the theory of positive protection operates either: through property regimes, liability regimes or as combined systems containing both...[wherein] a property regime vests exclusive rights in owners, of which the right to refuse, authorize and determine conditions for access to the property in question are the most fundamental. On the other hand, a liability regime is a "use now pay later" system according to which use is allowed without the authorization of the right holders. But it is not free access because post compensation is still required.

[12] A detailed discussion of the work of the CBD on the protection of TK will be discussed in the next chapter.

[13] See article 3 to 8 of the Biological Diversity Act, 2002. A critical analysis of the Act will be done in the fourth chapter.

sales of any product developed from the knowledge. The money is paid into the Fund for the Development of Indigenous Peoples.

b) Commodification of Traditional Medicine

There are various plausible reasons to protect TK. Generally they may be categorized as commercial and social reasons.[14] Among the commercial reasons, a popular view is that TK should be protected because pharmaceutical corporations and bioprospectors are misappropriating it and making huge profits in the form of what is popularly known as biopiracy. Many critics condemn the northern "[c]orporations [that] are surveying remote areas of the world for medicinal plants, indigenous relatives of common food crops, exotic sweeteners, sources of naturally occurring pesticides...genetic material and knowledge of the indigenous peoples". The epithet "biological colonialism", "genetic imperialism", and even plain "plunder" dominate many instances of the biopiracy narratives (Chen 2006:).[15] The rampant commodification of the TK through its exploitation and appropriation has accelerated the debate of protecting TK and its subset TM. In most of the cases, developing countries were the victims of these misappropriations by the researchers, scholars and institutions from outside the community (usually western)[16] with neither the consent of the community, nor agreements to share benefits arising from the use of the knowledge, made them to counter the western "protectionist" measures in the form of IPR for the knowledge that was already known to this part of the world. In this aspect, India holds the view that:

> Rampant biopiracy deprives holders of traditional knowledge of any benefits. Loss of bio-diversity and associated traditional knowledge will not only deprive

[14] There could be many compelling reasons for the developing countries motivating to protect TK. In one of his study, Graham Dutfield (2000) suggests three broad set of reasons to protect TK. a) Moral b) Legal c) Utilitarian. According to him, the moral reasons are to fulfill the moral obligations towards the indigenous and local communities and to prevent biopiracy. The legal reasons are to comply with the obligations under the international treaties and emerging norms. e.g. CBD, UDHR, IUPGR. Lastly, the utilitarian reasons are for the welfare (economic, food security and health) of the communities and traditional knowledge holders; for the national economic welfare benefits; for global economic and welfare benefits and for an improved sustainable management of biodiversity and conservation (Dutfield 2000:10).

[15] For a developing country perspective on biopiracy, see generally Shiva, 2002; Shiva, 1998; Tokar, 1997.

[16] The actors in the process of misappropriation of the TK are not always, from the developed or western countries. Appropriation can also be done by the people of the same origin/country. A classic example of this kind is the Case of Turmeric, wherein in 1995, two Indian nationals at the University of Mississippi Medical Centre were granted US patent no. 5, 401, 504 on "use of turmeric in wound healing". The turmeric case was a landmark case as it was the first time that a patent based on the traditional knowledge of a developing country had been successfully challenged and was later on revoked.

> the world of a unique knowledge-base but also threaten the very survival of local communities. Intellectual Property Rights laws must benefit all holders of such IPRs equally – whether they are huge multinationals spending billions of dollars on research or traditional local communities where knowledge has simply been passed on to one generation to other (UNCTAD, 2002).

The above observation has emphasized on two reasons to protect TK benefits (economic) and threat to the survival of the local communities (social). Though economic reasons are the important reasons of protection, the social factors such as livelihood, conservation of the knowledge, tradition and cultures of the indigenous and local communities are equally important for a person to make justification for his advocacy of protecting TK.

c) Relationship between Traditional Medicine, Culture and Life Style: Issues of Conservation.

The second possible reason to protect TK is to improve the lives of the TK holders and communities. In most of the developing countries like India, TK accounts as a valuable attribute of the indigenous and local communities that depend on it for their health, livelihoods and general well-being. Traditional low-input agricultural systems, based on extensive and applied knowledge about natural processes and local ecosystems have successfully enabled millions of people to subsist for thousands of years in some of the most hostile environments (Dutfield 2006:3,4). However, many TK based agricultural systems have fallen into decline. Factors of this decline like impact of modernization/westernization on these communities, commercialization of agriculture with the introduction of export crops and spread of market economies, etc. have made the international communities take the initiatives to protect and conserve the biodiversity and the knowledge related to the use of biological resources.[17] The OAU Model Legislation for the Rights of Local Communities, Farmers and Breeders and for the

[17] The Convention on Biological Diversity, 1992 has provided for the conservation of biological diversity along other objectives as follows:

> The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriated funding [Article 1].

Regulation of Access to biological Resources also proposes that the purpose of these rights is to recognize and protect the multi-cultural nature of the human species.

Traditional and indigenous knowledge of the communities is considered as a manifestation of culture.[18] Protecting such an important element of heritage of a nation is an imperative in a situation where such heritage in under a threat of erosion. The current international negotiations on the issue of protection of TK, the term protection is mostly seen as providing a framework to encourage the maintenance of practices and knowledge embodying traditional lifestyles. But in its actual sense, protection as provided Article 8(j) of CBD also requires the promotion of the "wider application" of TK. Some describe protection in this context as "a tool for facilitating access to TK" and some say that preservation of TK is not only a key component of the right to self-identification and a condition for the continuous existence of indigenous and traditional peoples; it forms a central element of the cultural heritage of humanity.[19]

III.5. Traditional Medicine and Intellectual Property Rights

The application of existing IPR models to traditional knowledge in general has been extensively found in the literature[20] and debated at international level. Among them much attention is paid to the applicability of Patents for two reasons: (a) to protect TM by granting patents; and (b) to prevent patents on the TM in public domain. Theoretically patents protect the inventions which are new, non-obvious and capable of industrial application. Now the issue is to clarify whether TM fulfills the existing international patenting requirements such as novelty, inventive step and utility. This issue may need first examination.

It is argued that since TK is mostly passed from generation to generation or disclosed in various ways, it lacks in novelty for the purpose of intellectual property protection. The novelty requirement, as applied in most countries, prevents the patenting

[18] Dutfield expresses a view that "[t]he knowledge, innovations and practices of indigenous peoples and local communities are manifestations of their cultures. Protecting a people's culture means maintaining those conditions that allow a culture to thrive and develop further... Therefore, protecting a people's cultural heritage involves inter alia maintaining the link between a people and natural features of the landscape and naturally occurring species of plants and animals" (Dutfield, 1999:514).

[19] See generally Drahos (1997); Correa (2001).

[20] See generally, Dutfield (2000).

of information in the "prior art". However, not all TM is disclosed. There are cases in which TM is, and has always been kept secret. In specialized areas, such as knowledge dealt with by bone-setters, midwives or traditional birth attendants and herbalists, including knowledge of healing techniques and properties of plants and animal substances, access is restricted to certain classes of people.[21] It is also very difficult to prove the "inventive step" in case of a TM for its protection under the IP systems. This is mostly because TM is considered to be passed through generations thereby restricting to prove the inventive step. This problem becomes complex when the TM is held by group of people. As mentioned earlier that now the trend in most of the developed countries is to invest on the research and development of the TM, around 21,388 CHM-related patents under the International Classification of A61K35/78 are in the TIPO CHM (Hsiao 2007:6).[22] However, the methods of manufacturing TM may be different with that of the manufacturing of the allopathic drugs. In India, the Drugs and Cosmetics Act, 1940 (as amended in 1986) governs the manufacturing of the drugs of various ISMs.

Traditional Medicine as Prior Art: 'Prior Art' is considered as the information that has been published in a written form or has otherwise been made available to the public, for instance, through public use, in any country before the date of filing of a patent. However there are differences in the approaches of the countries in determining the prior art. For instance, Article 102 of the U.S. Patent Law,[23] which defines 'prior art', does not

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[21] In Kenya, for instance, a study on herbal medicine showed that most of the herbalists interviewed maintained the secrecy of their knowledge:

> In Kenya, among the members of the Kikuyu community, indigenous knowledge in some fields was a well guarded secret. For instance a person who had acquired special skills as a black smith would not allow just anybody to walk into his workshop and watch him make such instruments as spears, pangas, diggings hoes, etc. The skills of making such instruments were carefully guarded. Such a person would only train his son or a very close relative. The same case applied to herbalists. An intruder was always heavily fined in order to deter any attempt to steal such knowledge. The problem with this type of system is that such important knowledge was owned by and confined to a few family members and rapid development on innovations was hampered by secrecy" (Muchae 2000:6).

[22] The first step in CHM drug manufacture is to select the appropriate herb, which is then cleansed and rinsed. Afterwards, the clean raw materials will be softened and cut into standardized thin pieces. The raw materials will be processed and treated according to their various characteristics (this is to detoxify the plants). After that, the raw materials will be set and weighed according to their weight ratio adopted from ancient prescription. The processes that follow are extracting, filtering and concentration to stabilize the herbal extract. In the last stages, the extract will be granulated and sifted to be packaged into a final product. The final product is often referred to as scientific Chinese medicine (Hsiao 2007:6).

[23] Section 102 of the U.S. law which defines 'prior art' reads as follows:

recognize technologies and methods in use in other countries as prior art. If knowledge is new for the U.S., it is novel, event if it is part of an ancient tradition of other cultures and countries. The U.S Law only recognizes the prior art which is in use within the U.S or should be published if it is used in other countries. The Act does not recognize the unpublished knowledge used in other countries. Use in a foreign country therefore does not constitute "prior art" in U.S. patent law. Due to this provision, many patents were granted by the US Patents and Trademarks Office (USPTO) in the recent years. A great victim of these patents is the Indian traditional medicine and knowledge. Starting from the cases of Turmeric and Neem, the saga of granting of patents on the prior art and knowledge in the public domain is still continuing be it the case of patents on the anti-diabetic properties of Karela, Jamun and Brinjal or more recently a patent granted for practicing of Yoga in a steamed room.[24]

III.6. Conclusion

TK is a complex set of knowledge which is difficult to define in precise terms. TK is an accumulation of local wisdom transmitted from generation to generation in a trial and error process which has allowed for sustainable adaptations to local life, cultural and environmental conditions. The term TK is defined mostly in an inclusive manner without focusing on any specific subject matter. The elaborate definition of TK, for example given by the WIPO is a compilation of various forms of TK prevalent in different parts of the world.

With its multiple components, TM has specific characteristics influencing the extent to which IPRs may be applied. It is understood that TM includes materials, processes and methods of treatment, individually or collectively held, constituted by old and recently developed knowledge, largely but not totally disclosed and capable of generating commercial value at different points of the value added chain. Most

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35 USC 102: Conditions of patentability: Novelty and loss of right to patent. A person shall be entitled to a patent unless: A) The invention was known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by the applicant for patent. Or B) The invention was patented or described in a trade publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.

[24] For brief discussion on the Patents on Yoga, see The Times of India, 30 May 2007 at page 1 and 21.

importantly, TM has great value in many developing countries where it plays a crucial role in the health care systems.

Little attention has been paid to the basic issues such as the definition of TM, but one can say that traditional medical knowledge may be passed on orally from generation to generation, in some cases with families specializing in specific treatments, or it may be taught in officially recognized universities. Sometimes its practice is quite restricted geographically, and it may also be found in diverse regions of the world. A medical system is called "traditional" when it is practiced within the country of origin.

Discussions concerning the protection of TM under IPRs, have generally focused on the third parties' misappropriation, and on the benefits that some forms of IPRs (existing or to be created) may generate for TM holders. The determination of the subject matter for protection and how to interpret the term protection are not yet clarified. Many other issues like 'biopiracy' and 'misappropriation' have been used without making it clear the ambit these offenses. Though defining the term TM is important to formulate a better regime of protection, it is also important to look at the various possibilities of the proposals of protection. That is to say the feasibility of applying various forms of IPRs, such as patents, trademarks, trade secrets and geographical indications also need close examination and scrutiny. An analysis of the ongoing debates at CBD, WTO and WIPO on the issue of protection of traditional knowledge is very much relevant for this study and the same will be dealt in the next chapter.

CHAPTER IV

CHAPTER IV

INTERNATIONAL PROTECTION OF TRADITIONAL MEDICINE

IV.1. Introduction

Traditional knowledge (TK) and Traditional Medicine (TM) are currently debated at various international fora, where solutions of protection are sought. The important among these are the negotiations going on at the World Trade Organization (WTO) and initiatives taken at the World Intellectual Property Organization (WIPO). However these negotiations are essentially focused on the interplay between the existing intellectual property norms and the subject matter of TK and TM. Nevertheless, there are other existing international norms which address the issues of protection in different perspectives other than IPRs. The study, therefore proposes to examine both set of norms in an elaborative way.

IV.2. International Legal Norms and Traditional Medicine

While the emphasis in approaching the question of protection of TK has clearly been on the existing intellectual property treaties, there are a number of international treaties and drafts in other fields that consider cultural issues more significant. Our discussion on the protection of TM may begin with the examination of some of these international norms.

a) Human Rights Instruments

The Universal Declaration of Human Rights, 1948[1] (UDHR) establishes the "right of everyone to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits and also the right of everyone to protect their moral and material interests resulting from any scientific, literary and artistic production of which he is the author" [Article 27]. The same rights were reiterated in the International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR)[2] which

[1] The UDHR was adopted and proclaimed by the United Nations General Assembly resolution 217 A (III) of 10 December 1948.

[2] The ICESCR was adopted and opened for signature, ratification and accession by the UN General Assembly Resolution 2200A(XXI) of 16 December 1966 and has entered into force on 3 January 1976. The provision dealing with intellectual property is Article 15 which says:

The State Parties to the present Covenant recognize the right of everyone:

in Article 1 establishes the rights of self-determination, including the right to dispose of natural wealth and resources. This also implies a right to protect and conserve resources, including intellectual property right (Heath and Sabine 2003:73). The phrase in Article 27(1) of the Declaration, "to share the scientific advancements and its benefits" can be understood to require or at least encourage benefit sharing with the local communities.

The difficulty in directly applying the Convention lies, first, in the fact that in the case of TM, TK holders often would not be the authors, and, second, that ownership might be collective rather than individual (Mugabe 1998). This view is challenged by some scholars,[3] who emphasizes that "the communal /collective nature of the development and improvement of traditional bio-cultural knowledge". Yet they does not perceive this as an obstacle to patent protection, as in reality even formal inventions are rather developed by communities of scientists working in huge laboratory complexes. It is also emphasized further that "most bio-cultural communities function as, and are usually recognized as, legal persons for numerous purposes, including land ownership and succession to titles". It is also interesting to note that many countries which have established a *sui generis* system of protection of TK provide for community rights in TK rather than for rights of individual knowledge holders and inventors (For example: Brazil, Costa Rica, Panama) (WIPO/GRTKF/IC/3/7:8).

According to the International Labour Organization (ILO) Convention Concerning the Protection and Integration of Indigenous and Other Tribal and Semi-Tribal Populations in Independent Countries of 1957 (Convention 107)[4] as revised in June 1989 (Convention 169)[5], the governments shall promote "the full realization of the social, economic and cultural rights of these peoples with respect for their cultural and social identity, their customs and their traditions and their institutions [Article 2(2b)]." A

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a) To take part in cultural life;
b) To enjoy the benefits of scientific progress and its applications;
c) To benefit from the protection of the moral and material interests resulting form any scientific; literary or artistic production of which he is the author.

[3] For instance see Mgbeoji (2001).

[4] The Convention 107 was adopted on 26 June 1957 and entered into force on 2 June 1959. For the text of the Convention, see http://ilolex.ilo.ch967/cgi-lex/convde.pl?C107.

[5] The Convention 169 was adopted on 27 June 1989 and entered into force on 5 September 1991. For the text of the Convention, see http://ilolex.ilo.ch567/cgi-lex/convde.pl?C169.

recognition of collective ownership can be found in Article 13(1), according to which governments "shall respect the special importance and their cultures and spiritual values of the peoples concerned of their relationship with the lands or territories, or both as applicable, which they occupy or otherwise use, and in particular the collective aspects of the relationship". Article 14(1) specifies that "[t]he right of ownership and possession of the peoples concerned over the lands which they traditionally occupy shall be recognized. In addition, measures shall be taken in appropriate cases to safeguard the right of the peoples concerned to use lands not exclusively occupied by them, but to which they traditionally had access for their subsistence and traditional activities..."[Article 14].

The United Nations Declaration on the Rights of Indigenous Peoples, 2006[6] while [r]ecognizing and reaffirming that ... "indigenous peoples possess collective rights which are indispensable for their existence, well-being and integral development as peoples (Preamble)", the Declaration mandates the states to:

> [P]rovide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs [Article 11(2)].

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[6] The United Nations Declaration on the Rights of the Indigenous Peoples, 2006 was adopted by the UN Human Rights Council at its twenty first meeting on 29 June 2006, Council resolution 2006/2, as accessed on 1 January 2007. The declaration is an outcome of a decade long negotiations held by the open ended inter sessional working group which was established by the UN Commission on Human Rights through its resolution 1995/32 of 3 March 1995 with the sole purpose of elaborating a draft United Nations declaration on the rights of indigenous peoples, considering the draft contained in the annex to resolution 1994/45 of the Sub-Commission on the Promotion and Protection of Human Rights. The working group of the Commission on Human Rights to elaborate a draft declaration in accordance with paragraph 5 of the General Assembly resolution 49/214 of 23 December 1994 has held 11 sessions between 1995 and 2006. The Declaration is solely based on the report of the working group on its eleventh session, which took place in Geneva from 5 to 16 December 2005 and from 30 January to 3 February 2006 (E/CN.4/2006/79). It was adopted by a recorded vote of 30 votes to 2, with 12 abstentions.

The countries which voted in favour include: Azerbaijan, Brazil, Cameroon, China, Cuba, Czech Republic, Ecuador, Finland, France, Germany, Guatemala, India, Indonesia, Japan, Malaysia, Mauritius, Mexico, Netherlands, Pakistan, Peru, Poland, Republic of Korea, Romania, Saudi Arabia, South Africa, Sri Lanka, Switzerland, United Kingdom of Great Britain and Northern Ireland, Uruguay, and Zambia. Canada and Russian Federation have voted against while countries like Algeria, Argentina, Bahrain, Bangladesh, Ghana, Jordan, Morocco, Nigeria, the Philippines, Senegal, Tunisia, and Ukraine have abstained form voting.

However the above conventions are less considered in the current international negotiations on the protection of the TK and its subsets. Though the focus is on IP related treaties, a considerate importance is given to the Convention on Biological Diversity in terms of its relation with the TRIPS Agreement. A critical analysis of the negotiating strategies on the issue of the relationship between the TRIPS Agreement and the CBD will be dealt in the next part of this chapter.

b) Convention on Biological Diversity, 1992 (CBD)[7]

Starting from a clean slate, there has been a great deal of discussion about the protection of traditional knowledge, including TM, through the intellectual property system. It has been discussed at many forums, where a concern was expressed that the loss of biodiversity and associated TK will not only deprive the world of this unique knowledge-base, but also threaten the survival of local communities whose livelihood is dependent on this. The foremost among the initiatives taken on the conservation and sustainable use of the biological resources are under the CBD.

The protection of TK including its subset traditional medical knowledge arises under Article 8(j) of the CBD. The issue has become contentious at WTO with the adoption of its Doha Declaration 2001 which has expanded the ambits of the Agreement on Trade Related Intellectual Property Rights (TRIPs), in particular Article 27.3 (b) and mandated the TRIPs Council to review the implementation of the TRIPS Agreement under Article 71.1 and to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, genetic resources and other developments [Paragraph 19].

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[7] The Convention on Biological Diversity (CBD), was adopted at the United Nations Conference on Environment and Development (UNCED) popularly known as the "Earth Summit" held at Rio De Janario on 3-14 June 1992. Along with the CBD, a Declaration on Environment and Development (RIO-Declaration), a Programme of Action (Agenda 21), the United Nations Framework Convention on Climate Change (UNFCCC), and non-binding statement of consensus on Forest principles were adopted at the conference. The CBD came into force in 1993 with currently 190 States as its parties. Though USA is a signatory party to the Convention, it has not yet ratified the Convention which is considered as a serious draw back of the Convention. See generally, Anonymous (1998), "How the Convention on Biological Diversity Was Defeated", [Online: Web], as accessed on 23 March 2007 at URL: http://www.sovereignty.net/p/land/biotreatystop.htm

The principal objectives of the CBD are the conservation and sustainable use of biological diversity, and the fair and equitable sharing of benefits arising from its utilization. The Convention recognizes that the key of maintaining biological diversity depends upon using this diversity in a sustainable manner.[8] The Convention is also considered to have one of the most prominent provisions on TK. The key provisions related to TK and IPRs are in the Articles 8 (j), Article 15 and Article 19. The fact that Article 8(j) is part of a provision which focuses on *in situ* conservation indicates that negotiations considered conservation of TK as being most relevant to biodiversity management (Cullet P., 2005:292). The Convention says that, [e]ach Contracting party shall, as far possible and as appropriate:

> Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices [Article 8 of the CBD].

A plain reading of this provision makes it clear that indigenous and local communities have devised various technologies in their own traditional manner to conserve the environment in general and biodiversity[9] in particular for which the preservation is sought. Though the article does not provide a definition of TK, in one of its work on "Traditional Knowledge and Biological Diversity", the Conference of Parties to the CBD has defined the term TK as: "traditional knowledge ... is a term used to describe a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical

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[8] The Convention translates its guiding objectives of conservation, sustainable use and equitable sharing of benefits into binding commitments in its substantive provisions contained in Articles 6 to 20. These articles contain key provisions on, among others: measures for the conservation of biological diversity, both *in situ* and *ex situ*; incentives for the conservation and sustainable use of biological diversity; research and training; public awareness and education; assessing the impacts of projects upon biological diversity; regulating access to genetic resources; access to and transfer of technology; and the provision of financial resources.

[9] "Biodiversity" is defined as "the variability among living organisms from all sources including, *inter alia* terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part, this include diversity within species, between species and ecosystems" [Article 2, CBD].

observations about the local environment, and a system of self-management that governs resource use..." (UNEP/CBD/TKBD/1/2, paragraph 85).

The article neither stipulate any protection for TK nor it guarantees indigenous and local community's people any rights over their knowledge, nevertheless it does recognize their rights over their knowledge, innovations and practices. This conclusion can be drawn from the first part of the article because it merely calls upon Contracting Parties, "subject to their national legislation to respect, preserve and maintain...".

Article 15[10] of the Convention addresses the terms and conditions for access to genetic resources and benefit-sharing. It asserts the sovereign rights of nations over their natural resources, and their right to determine access, promoting access and their common use. It notes that access to genetic resources should be on the basis of prior informed consent, and on mutually agreed terms that provide fair and equitable sharing of the results of research and development and the benefits of commercialization and utilization. It also calls for the fair and equitable sharing of the benefits derived from the use of TK.

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[10] Article 15: Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this convention, the genetic resources being provided by a contracting Party, as referred to in this Article 16 and 19, are only those that are provided by Contracting parties that are countries of origin of such resources or by the parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that party.
6. Each contracting Party shall endeavor to develop and carry put scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such contracting Parties.
7. Each contracting party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Article 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising form the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon agreed terms.

For convenience this objective of the CBD will be referred as ABS – Access and Benefits Sharing requirement

Among others[11], the Convention states in respect of intellectual property, that access and transfer of genetic resources should be consistent with the "adequate and effective protection of intellectual property rights". Governments should put in place policies to ensure that, particularly for developing countries, access to genetic resources takes place on mutually agreed terms. It notes that patents and other IPRs may have an influence on implementation of the Convention, and governments should cooperate (subject to national and international law) in order to ensure that such rights are supportive of and do not run counter to the CBD's objectives [Article 16].

Although the Convention was adopted in 1992 and entered into force at the end of 1993, it was not until 1999 that work began in earnest to operationalize these provisions. Though the provisions of the Convention are binding, they are mostly not mandatory but recommendatory in nature. However, some of the state parties to the Convention have implemented the objectives and directives of the Convention.[12]

According to its prime objectives related to benefit sharing and prior informed consent which is accepted to be important for the developing countries[13], the Governing Body of the CBD has recently agreed guidelines on access and benefit sharing as a guide

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[11] The other provisions are as follows:
Article 10: *Sustainable use of components of biological diversity*
Paragraph C of this Article encourages protecting customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable requirements.
Article 16: *Access to and Transfer of Technology*
This Article contains the only direct references to IPRs. Thus, following its paragraph 1, State Parties undertake to provide and/or facilitate access and transfer of technologies to other parties under fair and most favorable terms. The only technology referred to is biotechnology, but article 16 is concerned with any technologies 'that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment'. Dutfield opines that "(t)he use of clauses like 'adequate and effective protection' in paragraph 2 of the article was specifically to establish a link with the TRIPS Agreement, which also uses this language" (Dutfield, 2000: 34).

[12] Especially laws relating to the protection and conservation of the biodiversity and the knowledge related to the biological resources were legislated at national level and regional level as well. The countries like India, Philippines, Panama, Peru, Brazil, etc have enacted legislation for the protection of the biodiversity of their respective states. Many other state's legislations in this context are in pipeline.

[13] The objective of ABS provided in the CBD is mostly described to be of particular importance to developing countries, as they hold most of the world's biological diversity but feel that, in general, they do not obtain a fair share of the benefits derived from the use of their resources for the development of products such as high-yielding varieties, pharmaceuticals and cosmetics. Such a system reduces the incentive for the world's biologically richer but economically poorer countries to conserve and sustainably use their resources for the ultimate benefit of everyone on Earth

to the member countries when drafting national legislation on the subject (UNEP/CBD/COP/6/6).[14]

The Guidelines are expected to assist Parties, Governments and other stakeholders in developing overall access and benefit-sharing strategies, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. More specifically, the guidelines are intended to help them when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing. A programme for capacity building is already under way to ensure that developing countries are in a position to effectively implement the guidelines and the corresponding provisions of the Convention.

The Guidelines identify the steps in the access and benefit-sharing process, with an emphasis on the obligation for users to seek the prior informed consent of providers. They also identify the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers and stress the importance of the involvement of all stakeholders. They also cover other elements such as incentives, accountability, means for verification and dispute settlement.

Finally, they enumerate suggested elements for inclusion in material transfer agreements and provide an indicative list of both monetary and non-monetary benefits. Although they are not legally binding, the fact that the guidelines were adopted unanimously by some 180 countries gives them a clear and indisputable authority and provides welcome evidence of an international will to tackle difficult issues that require a balance and compromise on all sides for the common good. This was reinforced by the call of the World Summit on Sustainable Development, held in Johannesburg in August/September 2002, for countries to negotiate, within the framework of the CBD, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. It is expected that the Bonn Guidelines

[14] Bonn Guidelines on "Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilisation" were adopted by the COP at its 6th meeting held at Hague in 2002 in the process of the implementation of Article 8(j) of CBD. The document is so named because of the location of the intergovernmental meeting in October 2001 that prepared the first draft at Bonn, Germany.

will form part of that broader framework and will serve as a vital tool for the full implementation of the Convention and the safeguarding of the natural wealth on which all human societies depend.

But some argue that countries face difficult decisions, both practical and conceptual, in putting benefit sharing into practice. First, the resources in question are often not "owned" by anyone in particular, but are the heritage of one or more communities, which are not necessarily cohesive, or all living in one country. Secondly, while some genetic resources can be traced to very specific areas and habitats, in other cases they comprise components from many countries, in which case benefit sharing arrangements will be totally impractical. Thirdly, because of the diversity of national circumstances or indeed those within nations in relation, for example, to their cultural, economic or institutional conditions, it is very difficult to devise legislation and practices Which cover that diversity in ways that facilitate implementation of such measures (WIPO-CIPR, 2002:84)?

c) Initiatives by the International Organizations

i) The World Health Organization (WHO)

The WHO considers the TM as diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well being, as well as to treat, diagnose or prevent illness. Since more than 80 per cent of the worlds population depends upon various systems of TM, the main aim of the WHO is to promote the use of the TM for the primary health care in order to achieve its ambitious goal of 'Health for All'[15], especially in the developing countries where access to the modern medicine is limited for various economic and cultural reasons.

[15] "Health for All by the Year 2000" was an ambitious and worthy goal of the International Conference on Primary Health Care held at Alma Ata, USSR in 6-12 September 1978. Primary Health Care Declaration of Alma Ata was adopted by the Member States of the WHO at the Conference which was jointly convened by the WHO and the United Nations Children's Educational Fund (UNICEF). The Conference drew representatives from 134 states, 67 international organizations and many non-governmental organizations from various states. For more details of the Conference, visit: URL: http://www.paho.org/english/DD/PIN/Number17_article_html

The debate of the protection of TM from its misappropriation and the debate of IPRs connected with the TM is not within the scope WHO's work on TM.

Through its Traditional Medicine Program (TMP),[16] WHO supports Member States in their efforts: to formulate national policies on traditional medicine; to study the potential usefulness of traditional medicine including evaluation of practices and examination of the safety and efficacy of remedies; to upgrade the knowledge of traditional and modern health practitioners; to educate and inform the general public about proven traditional health practices.

In its continuing work on the TM, WHO has adopted the Traditional Medicine Strategy 2002-2005 wherein it reviews the status of the TM/CAM globally, and outlines the WHO role and activities in TM/CAM. But more importantly it provides a framework of action for the WHO and its partners, aimed at enabling TM/CAM to play a far greater role in reducing excess mortality and morbidity, especially among impoverished populations. The Strategy incorporates four objectives:

- Policy – Integrate TM/CAM with national health care systems, as appropriate, by developing and implementing national TM/CAM policies and programmes.
- Safety, efficacy and quality – Promote the safety, efficacy and quality of TM/CAM by expanding the knowledge-base on TM/CAM, and by providing guidance on regulatory and quality assurance standards.
- Access – Increase the availability and affordability of TM/CAM, as appropriate, with an emphasis on access for poor populations.
- Rational use – Promote therapeutically sound use of appropriate TM/CAM by providers and consumers (WHO–TMS 2002).

For the initial four years, WHO has concentrated on achieving the first two objectives for the development and implementation of national TM/CAM policies, and promote safety, efficacy and quality of TM/CAM. This also included the strengthening of research methodologies and on increasing the quality and quantity and accessibility of

[16] TMP is adopted by the WHO in the year 1976 and it is undertaken through twenty collaborating centres of the WHO. The work of WHO's TMP is managed under the Department of Essential Drugs and Medicine Policies of WHO. More information about TMP can be found at the following URL: http://www.who.int/medicines

clinical evidence to support claims for TM/CAM effectiveness. In this connection WHO states that "the wealth of accumulated clinical experience and knowledge within traditional medicine deserves to be acknowledge and combined with the methodologically sound research into the extent and limitations of traditional practice. Patients, governments, traditional practitioners, and practitioners of modern medicine all stand to benefit from evidence-based practice of traditional medicine. The support of the scientific community and practitioners of modern medicine will be needed if traditional medicine is to be brought into mainstream health services" (WHO 2001).

ii) The United Nations Education, social and Cultural Organization (UNESCO)

The UNESCO jointly with the WIPO has developed a Model National Laws for the Protection of Expressions of Folklore against illicit exploration and other prejudicial Actions. There is hardly any mention of the TM in the work of the UNESCO.[17]

iii) Food and Agricultural Organization (FAO)

The protection of TK has been raised in relation to the definition and implementation of the concept of Farmers' Rights introduced during the revision of the International undertaking on Plant Genetic Resources for Food and Agriculture, which began in 1994. Article 9.2(a) of the final text, which was adopted as a new treaty by the FAO Conference in Rome in November 2001 requires measures for the protection of TK but, in view of the scope and purpose of the Treaty, it only refers to knowledge "relevant to plant genetic resources for food and agriculture".[18] It is noticed that Article 9.2(a) of the treaty is narrower in scope than Article 8(j) of the CBD, and would not apply, for

[17] Since the work of UNESCO is mostly concentrated on the Expressions of Folklore, the deeper discussion of this work is not within the scope of this study.

[18] The International Treaty on Plant Genetic Resources for Food and Agriculture, 2001 wherein Article 9(2) states:

> The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
>
> a) protection of traditional knowledge relevant plant genetic resources for food and agriculture;
> b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
> c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

instance to the knowledge relating to medicinal or industrial use of plant genetic resources (Correa 2001:22).

IV.3. Applicability of Intellectual Property Norms

Application of the existing intellectual property norms to protect traditional knowledge has been extensively examined in the literature[19] and has been debated at various forums.[20] With reference to the protection of traditional medicine, special attention is given to the patents regime because it is assumed that patents enables the exercise of exclusive rights over traditional medical knowledge or over its possible uses (Correa, 2001:3).[21] However, this view is contested who argue that intellectual property rights are not suitable to protect TK. It is argued that since the evolution of modern IPR regime, as it exists today, has essentially evolved in response to a need in the aftermath of industrial revolution within Europe (Hegde 2007) does not in principle provide protection for the knowledge of the traditional communities (Cullet 2005:287). The United Nations Committee on Economic, Social and Cultural Rights has also expressed the view that, the IPR framework as proved in the WTO-TRIPS Agreement is incompatible with the international human rights norms and also it hinges the rights of the indigenous and local communities over their natural resources and knowledge associated with those resources (ECOSOC 2006 E/C.12/GC/17).

As a whole the arguments for the protection of TK and its subsets available in the literature and also at important international negotiations are observed to be pro and against the application of the existing intellectual property rights regime. The arguments were noticed to be essentially either moralistic or emotive in nature (Raghavan 2001:7).[22]

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[19] See generally Correa (2001); Dutfield (2000) (2006); Raghavan (2001); Downes (2000). Gopalakrishnan (2005); Gibson (2004); Liu (2003); Heath (2003); Mugabe (1998); and Cullet (2005);

[20] The international negotiations for the protection of TK have been mainly carried out at WIPO, WTO and CBD. Considerable ground work was done by the UNCTAD as well. See generally UNCTAD's study on "Biotrade". For example: Anida Yupari (2000).

[21] Carlos Correa opines that, contrast to patents, trademark and geographical indications only protect signs used to identify products, not the underlying knowledge as such (Correa 2001a).

[22] According to the author, the moralistic arguments focus on the western impression that every person has a moral right to control the product of his or her labor or creativity whereas the emotive arguments (mostly propagated by the developing nations) on the other hand have focused on the economic realities of the developing countries with both developed and developing nations accusing the other of pirating information.

One important basis on which the IPRs were justified by the Western states is to prohibit piracy. The west always has accused the south for copying their inventions and hence they need to protect their intellectual creations through these intangible property rights. The same logic can be applied to the issue of traditional knowledge. Recent instances which are plenty in number shows that the multinational corporations of the developed states are now engaged in coming out with new products which are originally based on the knowledge that is either already in the domain of the public of the developing countries or its use known to the communities of the developing countries since long period of time. A common concern has been expressed that does it amounts to an invention which is essentially originated form the prior existing knowledge. Authors described this as the plunder of nature and that it is not an invention just because its use is new to someone. Drahos (1999) remarks that, "how many people would think that the rock they pick up in the park becomes an invention of theirs after they have washed and polished it?[23]

Developing countries have been continuously claiming that their knowledge has been explored for the research leading to high priced inventions, the benefits of which are reaped by the developed nations. They have also made proposals that compensation should be received for traditional biocultural knowledge due to the value created and time saved in identifying plants used in medicine or by cultivating specific crop varieties obtained through the labor and time invested in selecting, nurturing, conserving and improving traditional varieties over a long period of time (Jacoby 1997).[24] As said by David Downes (2000), based upon the moralistic argument, intellectual property rights are articulated as a balance between private benefit and public good, and that in the case of traditional knowledge the clear calculation to determine whether there has been inequality is not easy (Downes, 2000:261). Despite the fact that it is very complicated to assert the damage caused by the IPRs to the TK, the proposals of protecting TK have

[23] Drahos also comments, "One suspect that, if Mother Nature had a patent on a particular naturally occurring gene sequences, she would almost always win a patent suit brought against the alleged inventor, since typically all that happens in non-natural gene sequences is the removal of redundant condons. In essence the sequences are the same (Drahos 1999:441).

[24] Jacoby argues that traditional bio-cultural knowledge not only guides researchers, but also provides them with unique sources and materials. He also points out that several companies in the United States currently take ethno-botanical data as part of their research.

mainly focused on IPRs and the possibility of introducing *sui generis* systems into the existing IPRs regime. This part of the chapter examines the possibility and problems of applying the existing[25] intellectual property[26] systems for protecting TK.[27]

a) Patents

Debates on the protection of TK have been mostly focused on patents rather on the other forms of IPR's such as copyrights, trademarks and geographical indications. However, some[28] say that patents can be tool to protect TK while others[29] say patents erode the rights of the traditional knowledge holders.

Theoretically, a patent is a limited monopoly granted to an inventor or creator of a particular invention which satisfies the three requirements of novelty, non-obviousness and commercial application. A justification of IPR fall generally into two classes: desire based and utility based. However on third justification is considered separately which is specific to the situation of the developing countries. i.e. that a hard patent regime will lead t the transfer of technology to these countries and bring in much needed foreign investment (Chimni 1993:243).[30]

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[25] The existing frameworks of the intellectual property laws that are recognized internationally are those identified by the TRIPS Agreement and are governed by the WTO. They are:- Patents; Copyrights; Trademarks; geographical Indications; Protection of Undisclosed Information; Layout Designs of Integrated Circuits; and Industrial Designs [Part II, Sections 1 to 7 of the TRIPS Agreement]..

[26] The term "intellectual property" is defined in Article 2(viii) of the WIPO Convention 1967 to include rights relating to:

- Literary, artistic and scientific works;
- Performances of performing artists, sound recordings, and broadcasts; inventions in all fields of human endeavor;
- Scientific discoveries;
- Industrial designs;
- Trademarks, service marks, and commercial names and designations;
- Protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

[27] TK in this chapter essentially refers to its subset traditional medicine and does not consider the other forms of TK such as folklore; art and music, etc.

[28] See generally, Downes (2000); and Correa (2001).

[29] See generally, Dutfield (2001), 2003; and Shiva (2002).

[30] Patents are generally viewed as a means towards encouraging invention and innovation in society. Quoting Edwin Hetinger, Chimni opines that grant of property rights is a mere means to ensure that enough intellectual products and countless other goods based on these products are available to users (Chimni 1993:243).

There is an assumption that IPRs have been important driving forces of the developed world after the two world wars which were primarily evolved to protect mechanical and chemical innovations for which identifications of novelty, inventive step and the innovator is relatively straight forward and easily identifiable. It was noticed only in the past three decades that the current IPR regime fails to provide any rewards to the public-domain foundations on which the innovations may be based (Utkarsh et al 1999:1418). For example, the use of neem oil[31] as an insecticide or turmeric powder[32] as an antiseptic are part of public domain knowledge which could be built upon through small steps such as the process for increasing the life of azadirachtin, the molecule which is responsible for pesticidal properties of neem oil.

A patent is a statutory monopoly granted for a limited period of time by the state for inventions having commercial application. It encourages research and development by offering a reward for developing an invention and making it public after a specified period of time. Issues of patentability arise with respect to the traditional medicine. Traditional medicines are not limited to the medicinal practices of indigenous people. As mentioned earlier they include knowledge of traditional cures, the curing properties of herbs, leaves, and other treatments not known hitherto the rest of the world. It also includes the genetic makeup of people who are immune from diseases thus far considered incurable.

Unfortunately, most TMs in their natural form often do not qualify for a patent protection. In the United States of America, to qualify as an invention, an item has to be useful, novel, and non-obvious. Most jurisdictions apply this threefold test. More importantly, TRIPS has adopted a similar test.[33] Although TMs have many uses, they

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[31] Neem oil, a well known pesticide in many parts of India and also other neighboring countries, whose active particle, azadirachtin, breaks down quickly. W.R Grace & Co. a transnational corporation prepared a chemical treatment for stabilizing the azadirachtin thereby increasing its shelf life and making possible for it to be transported worldwide. This so called invention was protected through a US patent (No 5124349). See also section I.3 (B) of the first chapter at p. 7

[32] The US Patent Office granted a patent (No 5, 401504) after initial reluctance, on the use of turmeric in the powder form for wound healing, on the ground that such usage is not known in the US. However the CSIR from India could present textual evidence in an appeal before the US Court that such usage was known in India from centuries and hence not novel. Consequently the patent was revoked.

[33] Article 27(1) of TRIPS details that patents shall be granted provided they are new, involve an inventive step, and are capable of industrial application. The footnote to the term "inventive step" clarifies that the

often fail to meet the novelty and non-obvious requirements of patent applications. Anything already in the public domain is not considered novel as it is "prior art". Since traditional knowledge generally has been in public within the society for centuries, it falls within the public domain. The US Patent Law specifies that the invention should not be obvious to one skilled in the art [Sections 101, 102 and 103]. TK will not qualify for this test thereby making patent protection of this knowledge difficult. The fact that traditional medicine is generally held collectively or has been in the public domain and in most cases has been practiced from generations disqualifies itself from an IP protection. This is because, since it is held collectively, identifying the actual creator becomes difficult and since it is practiced over generations, the requirement of non-obviousness is not fulfilled, hence disqualifying from an IP protection. However, if the TM is of new origin and the holder of that knowledge is an individual, the three requirements of patentability are fulfilled and it may be protected by granting a patent. But the chance of having this kind of new traditional medicine is very rare.[34] However there are other possibilities to protect TM. Though more focus is made on patents, many authors[35] have suggested other forms of intellectual property rights which can be used as the effective tools to protect different aspects of TM. For example: geographical indications, trade secrets, trademarks, etc.

b) Geographical Indications

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin.[36] Most commonly, a geographical indication[37] consists of the name of the place

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term "inventive step" and "capable of industrial application" may be deemed to be synonymous with the terms "non-obvious" and "useful" respectively.

[34] See generally Liu (2003); In this article the author describes how the New Traditional medicine can be protected under the current IP laws. While focusing on possibility of applying patents for the protection of the new traditional Chinese medicine, he has also explored the possibility of other forms of IPRs such as trade secrets, geographical indications and trademarks, etc.

[35] David downs (2000) describes how intellectual property could be tool to protect TK. Among the other who supports this view directly or indirectly are Carlos Correa (2001a), (2001), Hans and Van (2003), Weeraworawit (2003), Gupta (2000), and Liu (2003).

[36] The TRIPS Agreement defines a geographical indication to be:

> [I]ndications which identify a good as originating in the territory if a Member, or a origin or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin [Article 22(1)].

of origin of the goods. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Such indications may provide a competitive advantage, both domestically and in the foreign markets, when a traditional medicinal product is associated with its geographical origin (Correa 2001a). The protection of TK by this area of law is yet to be explored.[38]

An essential condition for the recognition of a geographical indication is that specific characteristics of a product must be attributable to the geographical origin. In the case of traditional medicine, if a consumer can establish an association between the geographical origin and the characteristics or quality, geographical indications may be useful to enhance the commercial value of that particular product of traditional medicine. However it should be noted that the commercial value of geographical indications depends in adequate management practices and quality controls and marketing capabilities. Thus, legitimate users of geographical indications must establish the standards to be applied, and the monitoring mechanisms to ensure that the characteristics and quality if products confirm to such standards. They must also enforce their rights domestically and internationally. There are some examples of geographical indications linked to traditional knowledge especially traditional medicine which illustrate the potential use of such indications to protect traditional medicine. However, all this may not be possible for TM holders in most cases. Procedures for the international recognition of such geographical indications are still under negotiation in the framework of WTO (WT/MIN(01)/DEC/1). Developing countries have strongly advocated for the strengthening of protection of geographical indications for products other than wines and

[37] The Lisbon 20 Convention, 1958, recognizes geographical indicators and provides for a system of international registration. Article 2 of the Convention defines appellations of origin as "the geographical name of the country, region, or locality, which serves to designate a product originating therein, the quality and characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors". Article 5 of the Convention gives the details of international registration with the international bureau.

[38] David Downes (2000) asserts that this area has not been used as a mechanism for intellectual property protection and since it is only the possibility of protection within the patent law that has been examined. He also asserts that the geographical indications are especially suitable since they are based upon collective traditions and a collective decision-making process; they protect and reward traditions while allowing evolution; they emphasize the relationships between human cultures and their local land and environment; they are not freely transferable form one owner to another; and they can be maintained as long as the collective tradition is maintained.

spirits, which already receive an enhanced protection under the TRIPS Agreement. They mainly urged that the protection provided for geographical indications of wines and spirits [Article 23.1 of TRIPS] be extended to other products, particularly those of interest to developing countries (WT/GC/W/136). Along India, these proposals were also supported by the countries such as Cuba, Dominican Republic, Honduras, Indonesia, Nicaragua, Pakistan, the African Group and Venezuela.[39]

Correa opines that a better exploitation and promotion of traditional geographical indications would make it possible to afford better protection to the economic interests of the communities and regions of origin of the products (Correa 2001:11).

c) Trademarks Protection

Trademarks protect visually perceptible signs that distinguish the goods or services of different undertakings. Depending upon the national law, trademarks may be acquired through use or by registration. Since most of the traditional medicines are held collectively some suggest that 'collective marks'[40] or 'certification marks'[41] may be particularly suitable. It is generally opined that trademarks may be as important for the marketing if traditional medicine based products as for any other medicine, depending on the strength of the mark, the particular conditions of the relevant market and the prevailing prescription practices of the healers and physicians. Trademarks can also be useful to the local and indigenous communities if they decide to commercialize themselves certain products, provided that they are able to monitor its use and enforce

[39] See the country submissions made to the WTO-TRIPS Council: WT/GC/W/136, WT/GC/W/208, WT/GC/W/302, and WT/GC/W/282.

[40] Collective marks are trademarks which serve to distinguish the geographical origin or other common characteristics of goods or services of different enterprises which use the collective mark under the control of the owner. Collective marks are usually held by associations of enterprises which offer the goods or services offered under the mark. The regulations governing the use of the collective mark have to be included in the application for registration of the mark.

[41] Certification marks are trademarks used to identify a product which meets certain standards established, managed and enforced by an organization "competent to certify" the products concerned. The organization applies for the registration of the mark and if successful, becomes the trademark owner. Only manufacturers who offer products for sale made in organization to use the mark. Consumers thus benefit form knowing that the products concerned meet the required standards. In general terms, the difference between collective marks and certification marks is that the former may only be used by members of the organization, while certification marks may be anyone who complies with the relevant standards.

their rights in case of violation. The use of collective marks or certification may have the benefit of providing a specific badge if approval of a local or indigenous community, in addition to give an indication of geographically dependent qualities of products.

However, the effectiveness of trademarks as a means of promoting the commercialization of traditional medicine will depend on the title-holders' capacity to exercise their rights, so as to deter the commercialization of infringed products. Moreover the value of the trademarks as well as the geographical indications depends upon the capacity to establish and preserve product homogeneity and quality standards, and on investments, sometimes substantial, in promotion and marketing. In other words, protection by such signs does not automatically guarantee that they would generate added value for the right holders (Correa 2001a).

c) Trade Secret Protection

Trade Secret[42] protection is another mechanism for the protection of intellectual property rights in traditional medicine.

There are two important differences between patent and trade secret protection. There is no requirement that a trade secret be new or involve an inventive step as required for patent protection. Certainly if a trade secret is not new, then it may not be a secret and, therefore, not patentable. But a trade secret need not meet the more formal, rigorous standards of novelty and inventive step as required for patent protection. Second, a trade secret can, if kept secret, last in perpetuity. In contrast, patent protection generally lasts for only 20 years after the filing date of the patent application.

Some argue that trade secret law is possibly the best form of protection for the TK amongst the prevailing regimes of Intellectual Property.[43] This law has some application

[42] A trade secret can consist of any pattern, device, compilation, method, technique, or process that gives a competitive advantage. In corporate terms, even items or data such as customer lists, financial information, recipes for food or beverage products, technical products, and technical subject matter of a patent, marketing procedures, or a professional questionnaire can be protected by trade secrets. The object of the law is to prevent information (which is a secret having commercial value) within the control of a person form being disclosed to, acquired by, or used by others without consent, in manner contrary to honest commercial practices. See generally Raghavan (2001) and Lakotia (2001).

[43] The requirements for the protection of confidential information-or trade secrets-at the international level are summarized in the TRIPS Agreement, which reads as follows:

to traditional medicines, such as plant or animal matter used by traditional healers, and the ceremonies, methods or processes used by them in administering the traditional medicine. It has also application for the indigenous people's knowledge and their medical practices.[44] For the purpose of protection of the traditional medicine, trade secret would be more comfortable, essentially when the exact owner is not known as in many cases it is held collectively and when it is difficult to establish the inventive step of a particular traditional medicine. For instance, where TK is known among only a small, closed circle of traditional healers, or is passed down generation – generation within a family, the knowledge may not be generally known and may, therefore be protected as a trade secret. However there are some views[45] that trade secrets may be used more effectively to protect the ceremonies, methods and practices involved in a particular traditional medicine rather than for the actual medicinal product. This is because information that certain plants, animals or minerals have medicinal value may be more difficult to retain in confidence than ceremonies practiced by a traditional healer. Moreover, if a traditional medical knowledge is ancient, the prospect of it being secret and, therefore, protectable as

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Natural and legal persons shall have the possibility if preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- has commercial value because it is secret; and
- has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret [Article 39.2 of TRIPS].

[44] There are instances where indigenous people have also tried to adopt the trade secrets strategy. Donald E, et al 2001, describes an example of a small tribe in Peru adopted this methodology to protect its property from California based Shaman Pharmaceuticals Inc. Shaman is a company based in San Fransisco. It focuses on isolating bioactive compounds from tropical plants having a history of medicinal use. The company's research team collects information on the use of plant medicines to treat various illnesses. Shaman, as part of its program, approached a particular tribe in Peru. The tribe/community demanded that they enter into an agreement with the company to get short and long-term benefits. The terms in the agreement addresses, reciprocity from the company to the tribe in three stages. The short term reciprocity addresses immediate needs of the community, like public health, forest conservation, and medical care. The medium-term reciprocity consists of benefits not immediately apparent, but nonetheless provides benefits before profit sharing might. These include providing equipment, books, and other resources. The long-term reciprocity involves returning a portion of the profits to the indigenous communities once a commercial product is realized. However, the company does not share the patents or part of the proceeds from the patents with the indigenous people who provided the initial material. The authors comment that "Long-term benefits will accrue in absolute terms only form intellectual property rights and not form the facilities that may be provided to the tribes. Nevertheless this is a good beginning. It will not be long before the indigenous people refuse to sign the dotted line unless the intellectual properties are shared".

[45] See generally Wielder (2001).

a trade secret is diminished. That is because over the years, a particular item of traditional medical knowledge may have been generally known. Therefore, question of the applicability of trade secret protection is very much fact dependent, and it has to be decided on a case-by-case basis. A decision will have to be made whether the elements for protection have been satisfied in a particular case and the question of ownership-individual or collective will also have to be resolved.

IV.4. Current International Negotiations on Traditional Medicine and Traditional Knowledge

a) WIPO Initiatives[46]

As the United Nations Specialized Agency responsible for the promotion of the protection of IP, WIPO has undertaken a programme in 1998 that explores emerging intellectual property issues. The programme for 2000/2001 covered: Firstly for protection of TK, innovations and creativity – including commissioning a study on customary law; regulatory systems that apply to the protection of informal knowledge; commissioning a feasibility study on the use of intellectual property law or practice to protect informal knowledge; and organizing a annual round table on the protection of traditional knowledge for the holders of such knowledge. The other issues of the programme are: biotechnology and biodiversity; protection of folklore; and intellectual property and development. In lieu of this programme, WIPO has constituted nine Fact Finding Missions (the FFMs)[47] in 1998 which were designed to enable WIPO to identify, as far as possible, the IP needs and expectations of TK holders.

For the 25th Session of WIPO's General Assembly in 2000, the Secretariat prepared a document which invited member states to consider the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional

[46] WIPO is one of the specialized agencies of the United Nations (UN) system of organizations established according to Article 3(i), Convention Establishing the World Intellectual Property Organization, 1967. The Convention entered into force in 1970. WIPO's mandate is the promotion of the protection of intellectual property (IP) throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization.

[47] The following are the nine FFMs constituted were sent to 28 countries of different regions. They are: FFMs to South Pacific; FFM to Eastern and South Africa; FFM to Caribbean; FFM to South Asia; FFM to West Africa; FFM to North America; FFM to the Arab Countries; FFM to South America; and FFM to Central America (WIPO-FFMs Report 1998-99).

Knowledge and Folklore (IGC). The IGC met for its first meeting in April 2001 and the delegations reported on the steps taken at the national level for the protection of TK. They were generally sympathetic with the idea of addressing the legal protection for TK under IPRs. The USA, however, questioned the desirability of establishing international rules on genetic resources, TK and folklore while other delegations indicated the need for further analysis on the matter (Correa 2001:22).

In the early years, most of the IGC's work on TK and on folklore (nowadays referred to more often as traditional cultural expressions) concentrated on defensive protection. More specially, the Committee has been considering ways to improve the availability to patent examiners of traditional knowledge and of publications describing TK. In addition, much discussion has covered disclosure of origin of genetic resources and/or related TK in patent applications, as at the CBD COP meetings and the WTO.

However, positive protection is increasingly being discussed in a substantive manner. The first shift in this direction came at the third session of the IGC in June 2002, for which WIPO prepared a paper called "Elements of a sui generis system for the protection of traditional knowledge" (WIPO/GRTKF/IC/4/8). It was given further impetus in Autumn 2003 when the WIPO General Assembly decided that the IGC's new work would focus particularly on the international dimension of the relevant issues and agreed that "no outcome of its work is excluded, including the possible development of an international instrument or instruments" (WO/GA/30/8, 2003).

The IGC has drafted two sets of provisions: the Provisions for the Protection of Traditional Knowledge and the Provisions for the Protection of Traditional Cultural Expressions.48 Both of these were presented at the eighth session of the IGC and will be further deliberated on at the ninth session. Both sets of draft Provisions are described as controversial. It is observed that, Norway has been seeking to push the process forward in a staged approach beginning with consensus on fundamental objectives and principles to be expressed in a non-binding declaration or recommendation (WIPO/GRTKF/IC/9/12). The ultimate expected outcome could then be a treaty but that would presumably come

[48] As revised for the eighth session of the IGC. See also annex to the document WIPO/GRTKF/IC/8/5, 2005 and reproduced in annex to document WIPO/GRTKF/9/5, 2006.

several years down the road. Nonetheless, despite the efforts of countries that would like to see meaningful results, there still remains a strong possibility that these texts and the processes which are pushing them forward will follow the Substantive Patent Law Treaty text and process in running into the sands of stalemate and recriminations (Dutfield 2006:18).

Developed countries are least interested in having an international legal regime for the protection of TK because there is little to gain out of such regime. Even some of the developed countries are also becoming rather negative about the IGC. The assumed reason for this is, first, they can never get the international treaty on TK that they seek through IGC. Second, that the Committee's very existence serves as a justification for developed country opponents to actively keep the subjects of TK and ABS out of negotiations on intellectual property are the WTO and other WIPO forums using the argument that these are matters exclusively for the IGC to deal with. Dutfield opines that, as for TK holders and their representatives, they have serious concerns that WIPO's mandate to promote intellectual property conflicts with their wish to toll back IP regimes they find intrusive, and that the IP focus of an discussion on TK, inevitable perhaps for such an organization, is too constraining since it reduces a highly complex issue to the technicalities of the formal IP rights of patent, copyright, trademarks, trade secrets and geographical indications (Dutfield 2006:19).

b) Traditional Medicine, Traditional Knowledge and the WTO

Even though TK was not an issue at the TRIPS negotiations during the Uruguay Round,[49] it has been one at the WTO almost since the organization came into being (WTO Doc.IP/C/W/216: para 36). As early as June 1995, it came up in a meeting of the Committee on Trade and Environment. At that particular meeting, the Nigerian delegate argued that TRIPS must be construed to "accord recognition to traditional interest and right holders". In addition, the Indian representative complained that "the worst casualty, in an IPR regime for plant varieties, was the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the

[49] For better understanding on the introduction IPR regime in the WTO and its effects on the developing countries, see generally Chimni (1993); and for the response of the Asian African States to the new philosophy of intangible property rights, see generally Hegde (2007).

conservation and sustainable use of biodiversity, highlighted in Article 8(j) of the Biodiversity Convention" (WT/CTE/M/3). Since then, developing country's interest in TK has increased, which reflected in the frequent proposals from these countries at various fronts like CBD, the FAO and WIPO. These efforts of the developing countries have helped in mainstreaming TK to the extent that it emerged as an important issue at the WTO.

The process of review of Article 27.3(b) has actually started in 1999 with the following issues on the negotiating table:[50]

- Technical issues relating to patent protection under Article 27.3(b);
- Technical issues relating to *sui generis* protection of plant varieties;
- Ethical issues relating to patentability of life forms;
- The relationship to the conservation and sustainable use of genetic material;
- The relationship with the concept of traditional knowledge and farmers' rights.

According to a study made by UNCTAD-Secretary General, in the year 1999, more than half of the 250 proposals submitted to the WTO General Council during the preparations for the Seattle Ministerial Conference came from developing countries.

Of these 250 proposals, fifteen were on TRIPS and eight came from developing countries (UNCTAB/ITCD/TSB/10).[51] During the early stages of the twelve-month period leading up to the Seattle Conference, a year when Article 27.3(b) of TRIPS was scheduled to be reviewed, it seemed that the United States, the European Union, and Japan were going to seek to raise the standards of protection. For its part, the United States, in a communication to the WTO General Council dated November 19, 1998, noted in reference to the 1999 review that the TRIPS Council is "to consider whether it is desirable to modify the TRIPS Agreement by eliminating the exclusion from patentability

[50] See the submissions made by the Countries and the drafts prepared by the TRIPS Council during the initiations of the review process of Article 27.3(b) of the TRIPS Agreement.

[51] 1999 is described by Dutfield (2001:270) as remarkable year in the history of WTO negotiations which has clearly shown a paradigm shift in the negotiations and the balance of powers. While the Quad countries (the United States, European Union member states, Japan and Canada) were still disproportionately powerful, developing countries became more proactive and assertive. For a clear understanding of the propositions of the developing countries versus the developed countries, see Table 1 annexed to this Chapter at p.86, 87.

of plants and animals and incorporating key provisions of the UPOV agreement regarding plant variety protection" (WTO Doc.WT/GC/W/115).

A communication from the European Union to the General Council dated June 2, 1999, while adopting a conciliatory note, noted that "[i]t should of course be kept in mind that the TRIPS ... is a basis from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods (WTO Doc. WT/GC/W/193, para 3).

In a similar vein, a submission from Japan to the General Council dated July 6, 1999 stated that: "... taking into account the nature of the TRIPS Agreement, that is, a minimum standard of intellectual property protection, we should not discuss the TRIPS Agreement with a view to reducing the current level of protection of intellectual property rights. To the contrary, the TRIPS Agreement should be improved properly in line with new technological development and social needs. For example, the TRIPS Agreement should deal with higher protection of intellectual property rights which have been achieved in other treaties or conventions in other fora appropriately" [emphasis added] (WTO Doc. WT/GC/W/242: paragraph 6).

Developed Countries[52] wanted to convey that the only direction the international IPR regime should move is towards ever higher minimum standards and fewer exceptions. Developing Countries opposed this view saying that the impact of TRIPS continues to defy even the most sophisticated economic analysis, and many developing countries simply cannot fulfill their TRIPS obligations within the transnational periods (Dutfield 2001: 272). During this period pressure upon developing countries was mounted to fulfill their obligations under the TRIPS. Most of the developing countries were far from unresponsive to these pressures.

Developing countries have begun not only to complain in an organized fashion about TRIPS, but also to propose in a coordinated way. Thus, developing countries not only have actively opposed the raising of IPR standards, they have even proposed that TRIPS be revised in order to circumscribe certain rights, to maintain or expand the

[52] Developed Countries here generally refer to the USA, EU, Japan and Australia.

exceptions, and to create new IPR frameworks. As they themselves had a number of grounds for dissatisfaction with TRIPS, they decided it was time to place their concerns on the negotiating table, and TK was one of these issues.[53]

On August 6, 1999, two important documents were submitted to the General Council. One of these, from the Permanent Mission of Venezuela, proposed that the next review of TRIPS inter alia should "[e]stablish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders" (WTO Doc.WT/GC/W/282, paragraph 2).

The communication by the African Group of Countries, which attracted considerable NGO support worldwide, warned that "by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b)[54] is likely to lead to appropriation of the knowledge and resources of indigenous and local communities" (WTO Doc. WT/GC/W/302, paragraph 24).[55]A more detailed proposal for a legal framework on TK was submitted to the General Council on October 12, 1999 by the governments of Bolivia, Colombia, Ecuador, Nicaragua, and Peru (WTO Doc.

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[53] Other major issues were access to essential drugs and technology transfer. See Preparations for the 1999 Ministerial Conference: Implementation Issues to be Addressed Before/At Seattle: Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda, para. 27, WTO Doc. WT/GC/W/354 (Oct. 11, 1999), available at http://docsonline.wto.org/. See also Preparations for the 1999 Ministerial Conference: Implementation Issues to be addressed in the First Year of Negotiations, para. 27, WTO Doc. WT/GC/W/355 (Oct. 11, 1999), available at http://docsonline.wto.org/.

[54] Article 27.3 of the TRIPS Agreement allows WTO Members to make certain exclusions from patentability. Subparagraph (b) of that Article makes explicit reference to the need to protect new plant varieties either by patents or by an effective *sui generis* system or a combination of thereof. It reads: Members may exclude from patentability: "(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement" [Article 27.3(b)].

[55] This communication by the African Group of Countries has also proposed that after the sentence on plant variety protection in Article 27.3(b) "a footnote should be inserted stating that any sui generis law for plant variety protection can provide for [inter alia]: (i) the protection of the innovations of indigenous farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources" (WTO Doc. WT/GC/W/302, para 23).

WT/GC/W/362). Specifically, the document proposed that the WTO establish a mandate in a future trade round with three purposes:

a) To carry out studies, in collaboration with other relevant international organizations, in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights.
b) On the basis of the above-mentioned recommendations, initiate negotiations with a view to establish a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge.
c) To complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of this round of trade negotiations.

Communications made by India in 1999 did not constituted any formal proposals on TK. Nevertheless it did pointed out the necessity of reviewing TRIPS Agreement with regarded to patenting of life forms (WTO Doc.IP/C/W/161).

Based on the communications made by the member states, the WTO Secretariat took initiatives on the issue of TK, especially on the relationship between TRIPS and CBD, in particular with respect to Article 27.3 (b).[56] However the discussions were limited to the issues of plant variety protection and genetic resources.[57]

The issue of the protection of TK was first raised by India[58] during the preparations for the Doha Round of Negotiations, wherein it has proposed that "the patent applicants should be required to disclose the source of origin of the biological material utilized in their invention under the TRIPS Agreement and should also be required to obtain prior informed consent (PIC) of the country of origin". India has also pointed out that "there is a need to provide appropriate legal and institutional means for recognizing the rights of tribal communities on their TK based on biological resources at the

[56] See generally, WTO Doc.IP/C/W/175 and WTO Doc. IP/C/W/216.

[57] See for example, the background note prepared by the WTO Secretariat, in response to a request made by the Committee on Trade and Environment (CTE) for a factual paper on the relationship between the CBD and the TRIPS, in particular with respect to Article 27.3(b) (WT/CTE/M/21). See also IP/C/W/216.

[58] In its paper on "*Protection of Biodiversity and Traditional Knowledge*" (WTO.Doc, IP/C/W/198), in the year 2000, India reports its experience of biopiracy with the cases of patents claimed over turmeric, karela, basmati and the neem tree; another example is the case of the ayahuasca vine (a native plant of the Amazonian rainforest used by thousands of indigenous peoples of the Amazon for sacred religious and healing ceremonies).

international level. There is also a need to institute mechanisms for sharing of benefits arising out of the commercial exploitation of biological resources using such TK. This can be done by harmonizing the different approaches of the Convention on Biological Diversity on the one hand, and the TRIPS Agreement on the other, as the former recognizes sovereign rights of States over their biological resources and the latter treats intellectual property as a private right" (WT/CTE/W/156; IP/C/W/198, para 11).[59]

The issue was later raised by the African group in 2000 (also backed by others)[60] wherein there was a proposal for the inclusion of provisions into the WTO-TRIPS, to promote and not undermine the conservation and sustainable use of genetic material, and to prevent the associated biopiracy. And also to ensure benefit sharing and authorization of access to genetic material, contractual arrangements between developing country governments and entities seeking genetic material, require an enforcement mechanism at the WTO level (WTO Doc. IP/C/W/206).

These propositions were opposed by the developed countries[61] in the following lines. Firstly, it is claimed that the reason for the granting of patents on the knowledge of the traditional communities is not with the patent system, but it lies with the inaccessibility of such knowledge of the patent examiners world wide. For this establishment of a single data base, in which information regarding knowledge and practices of indigenous communities could be recorded to provide patent examiners around the world with a source of information organized it could be searched easily to determine, in appropriate cases, whether a claimed invention is new and non-obvious (WTO.Doc. IP/C/W/209).

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[59] Various suggestions have been advanced to extend protection to knowledge, innovations and practices. These include: (i) documentation of TK; (ii) registration and innovation patent system; and (iii) development of a *sui generis* system (WT/CTE/W/156; IP/C/W/198, para 15). Proposals of India in this document were strongly supported by Brazil in its communication to the General Council (WTODoc.IP/C/W/228)

[60] The other countries which made similar proposals were: Brazil (WTODoc.IP/C/W/228); Bolivia, Colombia, Ecuador, Nicaragua, and Peru (WTO Doc. IP/C/W/165); Kenya (WTO Doc. IP/C/W/163)

[61] These countries include USA, EU and Japan. See the communications made by these countries on the review of Article. 27.3(b) in IP/C/W/209; IP/C/W/162; and IP/C/W/236.

Secondly, the requirement of the disclosure of origin as proposed by the developing countries would go beyond the obligations of both the conventions i.e. CBD and the TRIPS and hence does not favour incorporating into the TRIPS Agreement overly complex requirements which would oblige patent applicants to provide, in their patent application, an official certificate of the source and origin of the genetic material and the related traditional knowledge used, evidence of fair and equitable benefit sharing and evidence of prior informed consent from government or local communities for the exploitation of the subject matter of the patent (WTO Doc. IP/C/W/236).

Thirdly, the benefit sharing arrangements could be done through contractual agreements between the individual state governments and the private entities that wishes access to the biological resources and the conditions of payment, therefore, should be determined by the contractual agreement concluded at the time of access.[62] For the sake of balanced benefits of holders of biological resources and inventors/patentees, it is also appropriate that the benefit sharing be determined upon mutually agreed terms (WTO Doc. IP/C/W/254).

Lastly, with regard to the compatibility of the CBD with the TRIPS Agreement, it was agreed that the purposes of both instruments are widely disparate, and unrelated in any way. Where there might be a relationship in provisions, the agreements are sufficiently flexible to enable a country that is a member of both to implement the provisions of each in good faith in a non-conflicting and, in some cases, mutually supportive way. There is, therefore, no need to consider amending the provisions of either agreement to accommodate the implementation of the other (WTO Doc.IP/C/W/209).

The WTO Doha Declaration was adopted by the member states at the Doha Ministerial Conference in 2001, wherein the voice of the developing countries could steal

[62] See also the Annex to the Communication of EU (WTO.Doc.IP/C/W/254-Annex) for a Paper on the relationship between Intellectual Property Rights (IPRs) and Biodiversity submitted by the EU to the CBD Secretariat on 5 February 2001, in accordance with Decision 26 of the fifth Conference of Parties (COP V) of the CBD.

place among several other[63] important issues, with the inception of paragraph 19 which says:

> We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension (IP/C/W/347/Add.1; WT/CTE/W/210, paragraph 19).

Doha is described as a technical mandate that requires review (not necessarily amendment) of TRIPS within the existing international framework (Gibson, Johanna, 2004). Since the Doha Declaration, there is increased political pressure to conduct a review of obligations to protect traditional knowledge and the patenting of genetic resources. Together with the discussions in the WIPO IGC and the work of specific task forces, this has motivated changes to the system of International Patent Classification (IPC) to include a new category of information in traditional knowledge, specifically traditional medicine based upon plants. This is part of the imperative to document traditional knowledge as prior art.

As a contribution to the Doha mandate, a joint proposal[64] was made in June 2002, to amend the TRIPS to provide that WTO member states must require "that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights: i) disclosure of the source and country of origin of the biological resources and of the traditional knowledge used in the invention; ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and iii) evidence of fair and equitable benefits sharing under the national regime of the country of origin (WTO Doc. IP/C/W/356).

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[63] The other important issues included in the Doha Round of Negotiations are: Agriculture, Services, Market Access for Non-Agricultural Products, TRIPS, Relationship between Trade and Investment, Interaction between Trade and Competition Policy, Special and Differential Treatment, trade facilitation, WTO rules, Dispute Settlement Understanding, trade and environment, etc

[64] The proposal was submitted to the Council of TRIPS in June 2002 by Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe.

As at the CBD COP and at WIPO, disclosure of origin has been debated at some length, and several follow-up proposals have been tabled. The most recent of these, in May 2006 was a joint proposal submitted by Brazil, Pakistan, Peru, Thailand and Tanzania that would form an additional section of TRIPS, namely Article 29 bis ("Disclosure of origin of Biological Resources and/or Associated Traditional Knowledge"). The most substantial part of the document is paragraph 2, which states as follows:

> Where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin. Members shall also require that applicants provide information including evidence of compliance with the applicable legal requirements in the providing country for prior informed consent for access and fair and equitable benefit-sharing arising from the commercial or other utilization of such resources and/or associated traditional knowledge (WT/GC/W/564).[65]

In a revised proposal, Brazil, India, Pakistan, Peru, Thailand and Tanzania, subsequently joined by China and Cuba, suggest creating a new Article 29bis in the TRIPS Agreement with the express purpose of "establishing a mutually supportive relationship" between the TRIPS Agreement and the CBD (WT/GC/W/564/Rev.1). This marks the first time the countries, which call themselves the "Disclosure Group", has tabled specific text on a disclosure requirement. However, in November 2005 India had proposed text for the Hong Kong Ministerial Conference that would have launched negotiations on amending Article 27.3b of the TRIPS Agreement to include a disclosure requirement (see). Although Article 27.3b is the subject of both Doha Declaration mandates insofar as it covers exemptions to patentability for plants and animals, experts suggested that the change in strategy amongst the Disclosure Group in advocating for a change in Article 29 would help incorporate the proposed disclosure requirement into current TRIPS rules on information that patent applicants must disclose, including a description of the invention.

[65] For a commentary on the proposal of Article 29 *bis* to the TRIPS Agreement, see Bridges Trade BioRes, 9 December 2005 and 16 June 2006.

However, one has to wait and see whether these proposals would bring in new changes to the TRIPS Agreement. Experts on the subject opine that, "it seems highly unlikely that a new framework to protect TK will be inserted into TRIPS anytime soon. And since the United States is determined to prevent a WIPO convention on TK that could then be incorporated in TRIPS, this is unlikely to happen even in the more distant future". Dutfield has expressed a view that WTO would not be the most appropriate venue for establishing new norms on positive traditional knowledge protection that would require the insertion of additional text to the TRIPS Agreement or the possible deletion of existing text. A modest amendment aimed at improving access to medicines involved a considerable amount of effort and it is hard to imagine the achievement of the more substantial revisions that positive TK protection would entail" (Dutfield 2006:21).

At best, minimalist measures to safeguard TK from misappropriation could conceivably be agreed upon. A greater danger is that trade negotiators will sacrifice the interests of traditional knowledge holders once concessions in other areas of intellectual property or other trade-related issues are secured in return. In fact, for developing countries, TK serves a strategic purpose at the WTO that is unlikely to serve the interests of traditional peoples and communities. While some trade negotiators and ministries may see TK as a significant moral or economic issue, it is difficult to imagine many developing countries pursuing this issue with any great determination. Measures to protect TK are far more likely to be achieved at the international level by the CBD COP. And for governments genuinely interested in TK, whether out of a sense of social justice or because they believe TK can benefit national economies, solutions need to be found at the national level. These solutions have more to do with basic human rights than with intellectual property rights.

IV.4. Protection of Traditional Medicine: *Sui Generis* Models

a) The African Model

Africa is, economically, the least developed continent in the world, yet probably the most endowed in terms of natural resources. The continent is particularly rich in traditional knowledge associated with biological resources, medicinal plant diversity, the value of which is yet to be studied, discovered or quantified. It is generally claimed that

Africa has always maintained, conserved and nurtured its biological resources through generations of local and indigenous (traditional) communities – particularly through the activities of farmers, hunters, fishermen, women and local healers whose livelihood depends almost exclusively on these resources and that they have cared for the critical balance of the ecosystem and their biological resources in their own self-interest to survive (Ekpere 2002).

It was felt that for Africa, "classical" intellectual property rights on biological diversity could have profound implications which cannot protect traditional and indigenous knowledge. During the negotiations of the Uruguay Round as well as the Earth Summit, the Organization of African Unity (OAU)[66] was an active participant. Through its Scientific, Technical and Research Commission (STRC), OAU identified the problem of ownership, conservation and utilization of Africa's bio-resources as an important area of research and development. This concern was expressed in Kampala, Uganda, during the 5th OAU/STRC Meeting of Experts and symposium on Traditional African Medicine and Medicinal Plants (1996). This meeting mandated the STRC to organize a joint workshop on Medicinal Plants and Herbal Medicine in Africa: Policy Issues on Ownership Access and Utilization.[67] Another group of scientists unknown to STRC were also working to develop a common negotiating position at the various biodiversity related fora. Both groups found a common ground for collaboration and at a joint meeting held in Addis-Ababa (April 1998), a draft legislation on Community Rights

[66] The Organization of African Union was established in 1963 with 53 member states. Its intended purpose was to promote the unity and solidarity of the African States and act as a collective voice for the continent. It was also dedicated to the eradication of colonialism and established a Liberation Committee to aid independence movements. OAU along with the African Economic Community were amalgamated into African Union (AU) in 2002 with the adoption of the Constitutive Act by the Heads of State and Government of the Member States of the OAU. The purpose of the union is to help secure Africa's democracy, human rights, and a sustainable economy, especially by bringing an end to intra-African conflict and creating an effective common market. For details on AU, visit http://www.africa-union.org/

[67] The recommendations of the workshop included:

- The STRC should initiate and coordinate the process of drafting a model law on the problem of indigenous knowledge on medicinal plants;
- Establish a working group of experts to deliberate, coordinate and harmonize existing national policies on medicinal plants and put in place a common policy on sustainable use of medicinal plants;
- Assist African Union members to ensure that policies on ownership, access, utilization and conservation of medicinal plants are drawn up in consultation with other Union members at 3 the sub-regional and regional levels since political boundaries are not necessarily ecological boundaries.

and Access to Biological Resources (originally developed by the Ethiopian Institute for Sustainable Development (ISD)) was discussed and adopted as The Africa Model Legislation. This Model legislation was further endorsed at the 68th Ordinary Session of the Council of Ministers of the OAU held in Ouagadougou, Burkina Faso in 1998.

The (OAU) AU Model Legislation on the Protection of the Rights of Local Communities, Farmers, Breeders and Regulations of Access to Biological Resources is the document assisting the Union members to formulate their national legislation in accordance with their national interest, economic development objectives and political orientation. This initiative, often described[68] as a *"sui generis"* system of protection of the rights of the local communities, farmers, breeders and access to the biological resources was operationalized through a series of regional, sub-regional and national consultations of stakeholders and informed public debates. The objective of this model legislation is to give reasoned attention to agricultural development, indigenous knowledge system, conservation and sustainable use of biological resources, community rights, equitable sharing of benefits and national sovereignty consistent with the provisions of the CBD. The African Union members are provided with a framework for the formulation of legislation relevant to their national interest and protection of new plant varieties, using a similar process of stakeholder involvement, national dialogue and public debate.

The principal objective of the AU Model Law was to ensure the conservation, evaluation and sustainable use of biological resources, including agricultural, genetic resources and medicinal plants as well as associated indigenous knowledge in order to improve their diversity as a means of sustaining the life support systems. It was mainly developed with a view to prevent the disruption of African rural life, health and food production which could result from loss of: Seed and other planting materials, which are the foundation of all agricultural production; Traditional medicinal plants, the basis of health care delivery service for the majority of African people; Natural fiber and dyes, the basis of African arts and crafts etc, and to safeguard the vital interest of Africa from the consequences of globalisation and trade liberation.

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[68] See generally Adeniji, Kolawole O. (undated), Ekpere (2000), and Ekpere (2002).

Some peculiarities of the OAU Model Law are:[69] food security; sovereign and inalienable rights; community rights; importance of community knowledge and technology; participation in decision making; regulation of access to biological resources; prior informed consent; and fair and equitable sharing of benefits. The law aims at promoting the conservation of local biodiversity – related technologies, innovation and practices, food security as well as community rights over their biological resources and knowledge. It recognizes farmers' rights, as counterbalance to breeders right and thus ensures farmers tradition to save and exchange seeds and where necessary produce farmers certified seed.

The Law proclaimed that the Community rights are inalienable and owes the states with the responsibility to protect such rights. It is based on the principle that the TK, technologies and biological resources of local communities are as a result of the tried and tested practices of several past generations and that they are held in trust by present generation and no one has the right to create exclusive monopoly rights over them. The Law also recognizes the rights of the local communities are the custodians of their biological resources, innovations, practices, knowledge and technologies which are governed completely or partially by their own customary laws. The effective participation of the communities in the regulation access and sharing of benefits accruing from the utilization of their biological resources, knowledge, technologies and practices is ensured under the model.

The Law provides for a system to regulate access, subject to Prior Informed Consent (PIC) of the state and local communities. The Law recognizes benefit sharing as a right of local communities. It stipulates that a negotiated percentage of any financial or non-financial benefit be shared with the local community similar to that of the CBD provisions on access and benefit sharing.

[69] The specific provisions of the OAU Model law concerning the protection of traditional knowledge are: Part III and Part IV which prescribes for the Access to genetic resources, benefit sharing and the community property rights.

b) The Asian Model[70]

Next to Africa, Asia is the continent with rich biological resources. Efforts for the protection of TK were carried out mainly at national level. The countries like, India, Sri Lanka, Thailand, Pakistan, and Bangladesh have enacted legislations for the protection of traditional knowledge, regulation of access to the biological resources and the benefit sharing arrangements. Among these countries, India has also amended its Patents Act for the exclusion of TK from patenting. Unlike the OAU, the Asian countries have not yet agreed for any set of guidelines or binding instruments. However, negotiations are already in place within the SAARC[71] Countries. A Draft instrument for SAARC Countries on protection of Traditional knowledge was adopted during a meeting held at Cochin, India in April 2006.

The objectives of the draft instrument are to repress the misappropriation of traditional knowledge, to regulate access to traditional knowledge, and to ensure the fair and equitable sharing of benefits arising from the use of traditional knowledge [Article 1]. The instrument provides for the access to the genetic resources and direct access or acquisition of TK from its holders subject to the prior informed consent of the holder of TK. Article 4, prescribes a criteria for eligibility for protection wherein it excludes the TM which is new. Unlike other international instruments on the subject, the draft provides various modes of protection such as: the laws on intellectual property, including unfair competition law and the law of unjust enrichment; the law of torts; liability or civil obligations; criminal law; laws concerning the interests of traditional and tribal peoples, and biological diversity; regimes governing access and benefit sharing; or any other law or a combination of any of those laws.

The draft also provides for the registration of the TK in the Traditional Knowledge Digital Library and for a defensive protection module. Article 13 says that

[70] In this context, the Asian Model refers to the initiatives taken at the South Asian regional level and especially refers to the SAARC model law on the protection of TK.

[71] The South Asian Arrangement for Regional Co-operation is an economic and political organization of eight countries in Southern Asia. The organization was established on December 8, 1985 by India, Pakistan, Bangladesh, Sri Lanka, Nepal, Maldives and Bhutan.The Draft Legal Instrument for SAARC Countries on Protection of Traditional Knowledge was introduced in the "WIPO Asia-Pacific policy Forum on Traditional Knowledge and Traditional Cultural Expressions" organized by the WIPO in cooperation with the Government of India held at Cochin (India) in April 4 to 6, 2006.

"with a view to opposing pending patent applications, disputing granted patents or otherwise intervening in the grant of patents for products or processes invented or developed on the basis of traditional knowledge, the Competent Authority shall send the information entered in the TKDL to the main patent offices or the world in order that it may be treated as prior art in the examination of the novelty and inventiveness of patent application". Finally the draft gives utmost importance to the customary practices, norms, laws and understandings of the holder of the knowledge, including the spiritual, sacred or ceremonial characteristics of the traditional origin of the knowledge.

Though the draft is legally not in operation, the provisions of the draft have been implemented in many of the SAARC countries domestic laws on the protection of TK and the access to genetic resources. As said earlier, the Asian Countries are not only rich in biological resources but it South Asian region is also rich in practicing traditional medicine. South Asia is known as a hub of the famous systems of traditional medicine which have been in existence since time immemorial. As mentioned earlier, in the recent times there have been plenty instances of the misappropriation of the TK and TM of the developing countries, many of the Asian countries have enacted legislations in respect of TK. The following is brief analysis of the legislations of the South East Asian country – Philippines national legislations on the protection of TM.

c) National Legislative Efforts: The Case of Philippines

In Philippines, there are no existing IPRs 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.[72] Nevertheless, there were measures on how to protect TK. These measures draw their mandate from XIV Section 17 of the 1987 Constitution, which provides the fundamental legal basis for the protection of TK. According to this article:

> The State shall recognized, respect and protect the rights of the indigenous cultural communities to preserve and develop their cultures, traditions and institutions. It shall consider these rights in the formulation of national plans and policies.[73]

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[72] Philippines -South East Asian island country is mainly agriculture dependent country and is known for its rich cultural heritage and TK. It is also the first country to introduce bioprospecting regulations.

[73] The "system" is not a single law, but consists of the following instruments:

The purpose of the new system EO 247/IPRs is "to regulate the prospecting of biological and genetic resources so that these resources are protected and conserved, are developed and put to the sustainable use and benefit of the national interest". According to the preamble, it is in the interest of the State's conservation efforts "to identify and recognize the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use. The law provides for the active control of the states over its biological resources. However, the state's authority is not absolute, in that prospecting is only permitted within "the ancestral lands and domains of indigenous cultural communities...with the prior informed consent of such communities; obtained in accordance with the customary laws of the concerned community". Permission for bioprospecting depends on a research agreement between the bioprospectors and the government.

Under the Indigenous Peoples Rights Act, 1997 (IPRA), the indigenous cultural communities/peoples are entitled "to their ancestral domains to ensure their economic, social and cultural well being and shall recognize the applicability of customary laws governing property rights or relations in determining the ownership and extent of ancestral domain". Chapter VI of IPRA deals with cultural integrity, and has the key provisions on community intellectual rights, rights to religious, cultural sites and ceremonies; right to indigenous systems and practices and to develop own science and technologies and access to biological and genetic sources.

Another important piece of legislation, "the Traditional and Alternative Medicine Act, 1997 (TAMA) or Republic Act 8423", institutionalizes the ownership by indigenous societies of their knowledge of traditional medicine. According to this law, when such knowledge is used by outsiders, the indigenous societies required the permitted users to

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1. Executive Order No. 247, "Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes" (1995).
2. The EO 247 "Implementing Rules and Regulations" (1996); and "The Indigenous Peoples Act" (1997)

acknowledge its source and demand a share pf financial return that may come from its authorized commercial use [Section 2].

Philippines has also undertaken a process of documenting and making an inventory of plant and genetic resources and knowledge originating form indigenous and local communities. Critiques argue 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 commercialized 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 (Domingo-Morales 2002:1). However, the Philippines laws were considered as trend setter for such kind of national systems to be developed through processes of consultation with civil society organizations and indigenous and local communities.[74]

IV.5. Conclusion

To summarize the international policy discourse and the negotiations strategies of the north and south on the protection of TK, one can say that the there is a tendency to consider Patents as effective tools f protection. Though some scholars have propagated the idea of utilizing the other forms of IPR such as trade secrets and geographical indications, countries have shown least response to these modalities. The requirements of compulsory disclosure of origin of the biological and genetic resources, prior informed consent and the rules regarding access and benefit sharing as projected by the developing countries and contested by the developed seems to be far from the existence. The negotiation process clearly shows that developed countries especially backed by the US do not want legislation on TK because of its least returns to these countries.

Proposals to have *sui generis* systems of protection were made, but the elements of such a system are not made clear in any of these proposals. The practical difficulties in applying the IPRs for the protections of TK are not made clear. States are now engaged in implementing their obligations under both the international instruments, i.e. CBD and

[74] Countries like Pakistan and Bangladesh are in the process of enacting the: "Legislation on Access to Biological Resources and Community Rights" (Dratt) of Pakistan; "Biodiversity and Community Knowledge Protection act of Bangladesh" (Draft) of Bangladesh.

the TRIPS. There is growing tendency of entering into the regional arrangements for the protection of TK, for instance the OAU Model, the Model guidelines for the Andean Communities and the draft instrument of SAARC on TK. However all these efforts are still in evolving stage and, nothing constructive has been agreed or enacted yet at international level. But one positive sign from efforts of the some countries is that they have already brought legislations governing the access and benefit sharing of the biological resources and have also amended their IP laws in order to accommodate the interests of the TK holders. A best example can be cited of India, which has enacted the Biological Diversity Act, 2002 and the Patents (Amendment) Act, 2005 in response to its obligations under the CBD and the TRIPS respectively. Also India has already a well established system of regulating the traditional systems of medicine. A study of Indian legislation on the regulation of TM and the initiative taken by Indian government for the protection of TK in general and TM in particular is dealt in the next chapter.

Table 1: Proposals for Review of Article 27.3(b) of TRIPS

Developing Countries Proposals	Developed Countries Proposals
African Group -Review should clarify that plants, animals, micro-organisms, their parts and natural processes cannot be patented. - Harmonize TRIPS with CBD. -TRIPS should contain provisions to prevent biopiracy. -increase scope of Art. 27.3(b) to include protection of indigenous knowledge and farmers' rights -Sui generis laws should allow for protection of community rights, the continuation of farmers' practices and the prevention of anti-competitive practices which threaten food sovereignty. Asia (India, SAARC and Singapore) - Harmonise TRIPS with CBD either by requiring information on providers of genetic resources and countries of origin of biological material under TRIPS Art. 29, or by incorporating a provision that patents inconsistent with CBD Art. 15 must not be granted. - Exclude patents on all life forms. If this is not possible, then at least exclude patents based on traditional/indigenous knowledge and products and processes essentially derived from such knowledge. - There must be disclosure of the country of origin of the biological resource and associated knowledge, and proof of the provider's consent, to ensure equitable sharing of benefits. - It should be left to national policy to decide what are patentable micro-organisms, including in light of Art. 27.2 (morality and order public). - It would be essential to ensure that the preservation of farmers' rights is not considered a dilution of effectiveness of the system. - What is an effective *sui generis* system may be best left to each Member to evolve in its legal system and practice - There is a need to prevent piracy of traditional knowledge built around biodiversity and to seek the harmonization of TRIPS with CBD to ensure appropriate returns to TM. Developing Country Group (Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe, Group of 77, LDC Group, Group of Cuba, Dominican Republic, Egypt, EL Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda). -Harmonization of TRIPS with CBD. -It should be clarified that the provisions on	European Union - No lowering of standards of protection - No extension of transition periods - The EU does not favor incorporating overly complex requirements which oblige patent applicants to provide an official certificate of the source and origin of the genetic material and the related traditional knowledge used, evidence of fair and equitable benefit sharing and evidence of prior informed consent from government or local communities for the exploitation of the subject matter of the Patent. The EU is open to other solutions on sharing information about origins of patented biological material. Japan - No lowering of standards of protection - A system under the UPOV Convention is an effective *sui generis* system - The proper balance between breeders' rights and farmers' rights will be solved by adopting a UPOV system. Norway - It should be considered whether a provision on the disclosure of the origin of genetic resources should be inserted in the TRIPS Agreement to ensure a more effective implementation of the CBD. - There should be flexibility with regard to the implementation of the *sui generis* option to allow for effective benefit sharing with indigenous and local farming Communities. Switzerland - No lowering of standards of protection - The exclusion for plants and animals is a balanced provision that takes into accounts members' needs and interests. - Agrees with Singapore that the UPOV system is a useful reference for the basic level of protection of any *sui generis* system for the protection of plant varieties. Nonetheless, also agrees that there may be other *sui generis* systems that meet the requirements of Article 27.3(b) besides UPOV and considers the elements listed by the USA to be helpful in drawing up such systems.

patenting of micro-organisms only apply to genetically modified micro-organisms.
-Should provide that where a country grants patent protection to plant based inventions, applicants are obliged to
(a) Declare the origin of materials and demonstrate prior consent of the country of origin and where relevant the indigenous or farming communities; &
(b) Pay compensation to the country or communities that had the material or the traditional knowledge used.
-Patents inconsistent with Art.15 of CBD should not be granted.
-Future negotiations must seek mechanisms for a balanced protection of biological resources and disciplines to protect TK.
-Need for extended transition period.

Latin America

(Bolivia, Colombia, Ecuador, Nicaragua, Peru, Brazil and Venezuela)
- The Ministerial Conference should adopt a mandate to:
(a) carry out studies in order to make recommendations on the most appropriate means of recognizing and protecting TK as the subject matter of IPR;
(b) initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of TK;
(c) complete the legal framework envisaged in paragraph:
(d) above in time for it to be included as part of the results of the new round of trade negotiations.
- Flexibility for members to decide on the most effective means of a *sui generis* system should be retained. UPOV is not the only reference to fulfill the criterion of effectiveness.
- Flexibility for members to exclude plants and animals should be retained.
- Art. 27.3(b) should be amended to allow members to require further conditions for patentability, viz (1) identification of source of genetic material; (2) TK used to obtain that material; (3) evidence of fair & equitable benefit-sharing; and (4) evidence of prior informed consent for the exploitation of the patent.
- Art. 27.3(b) should bear an interpretative note clarifying that discoveries or naturally occurring materials are not patentable.

Introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognize collective rights.

United States of America

- Eliminate the exclusion for plants and animals so that they must be patentable in all countries
- Incorporate UPOV 91 into TRIPS
- The US believes that an effective *sui generis* system would:
a) apply to all varieties in the plant kingdom;
apply to varieties that are new, distinct, uniform and stable; grant rights only to breeders;
b) grant rights of at least 20 year duration;
c) Prevent others from commercializing protected varieties without authorization; etc.

CHAPTER V

CHAPTER V

INDIA AND TRADITIONAL MEDICINE

"dharmartha kama moksanam arogyam mulam uttamam".

Charaka.

V.1. Introduction

Health is the chief basis for the development of ethical, economic, artistic and spiritual sides of man. Quoting the above *hymn* of Charaka, S. Radhakrishnan says that wealth of a country depends not merely in its natural resources, but also on the vitality of its people.[1] It is a widely accepted fact that the ancient Indian medicine had the proper outlook on problems of health and there was a belief that the achievements of Indians in the field of medicine are imperfectly known to the world even today (Kutumbaiah, 1962:1).[2] This assumption may not suit the current scenario. The rapid developments of technology have given the necessary impetus to the misappropriation of these medical achievements of India. Instances of processing of the molecules in the laboratories by most of the western companies to find out the medicinal characteristics of the herbs and plants used for various systems of traditional medicine (TM) in India and thereafter producing a new drug and granting patents for such newly created drug are increasing. To counter this misappropriation, India has voiced for the protection of the traditional medicine of India at various international fora. As mentioned in the earlier chapter, India has projected an idea of *defensive protection* to the international community at various fronts which was opposed by most of the developed countries that initiatives have to be taken at the national level and therefore there is no need of an international legislation for the protection of traditional medicine.

Now, a question arises whether India is deficient of any domestic legislation for the prevention of misappropriation or for protection? If it is not such, then why there were instances of misappropriation at all? Why is India claiming for an International

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[1] This quotation is taken from a foreword note written by the then President of India Dr. S. Radhakrishnan for the book "Ancient Indian Medicine" by Dr.P.Kutumbaiah (1962), Madras: Orient Longmans Ltd. While quoting a *hymn* by Vagbhata -*"yuganurupa sandarbho hy ayam sarah prakasyate"*, he says that "[t]he systems of medicine will have to keep pace with the developments of time. Our systems suffered because they were not able to reckon with the progress made".

[2] A western scholar, H.W.Rawlinson has also similarly observed that, "India suffers today in the estimation of the world, more through the world's ignorance of her achievements than in the absence or insignificance of these achievements" (Kutumbaiah 1962:1).

legislation? Whether the domestic legislations on the regulation of traditional medicine does not provide for protection? To answer these questions, a critical analysis of the legislations under which the traditional medicine was regulated is essentially required. In this chapter a review of the evolution and regulation of traditional medicine in the ancient, medieval and modern India is made. Along with this a critical analysis of the existing domestic laws of India regulating traditional medicine, the institutional mechanisms for the protection, and the effectiveness of these mechanisms is also made.

V.2. Status of Traditional Medicine in the Ancient Times and under the British Rule

India has a rich, centuries-old heritage of traditional health care systems. Ayurveda dates back nearly 7000 years. Siddha[3] also dates back approximately to the same period. It is believed that, Ayurveda used to be practiced in Northern part of India whereas Siddha in the Deccan region. In the ancient days, medicine in India was mostly dominated by magical and religious beliefs which were an integral part of almost all ancient cultures and civilizations flourished on the land. Although primitive man may be extinct, his progeny - the so called "Traditional Healers", are found everywhere even now. They live close to the people and their treatments are based on various combinations of religion, magic and empiricism (AYUSH webpage).

It is argued that India has a history of practicing medicine especially Ayurveda much before the British[4] and evidence for the existence of a well organized system of medicine in India can be traced back to archaeological remains of Harappa and Mohenjodaro where the evidences of 'tree-worship' were found; which indicates great importance of plants in human life (Sharma 1991:7). During its early period, it was perhaps the only system of overall healthcare and medicine which served the people in such crucial areas as health, sickness, life and death. Ayurveda enjoyed the unquestioned patronage and support of the people and their rulers in the ancient times. It is found by

[3] Unlike the other systems of Indian Medicine, Siddha was not so popular in the medieval periods. However, after the independence government has taken initiatives for the development of the Siddha Medicine in India after enactment of the IMCC Act, 1970. At present, there are seven Siddha institutions imparting education in Siddha System of Medicine in the country.

[4] O.P. Jaggi in his treatise mentions that "there is practically no knowledge of the practice of medicine in the British Isles until some years after the Norman conquest of England. Medicine became a profession after the Norman Conquest, though there does not seem to have been any systematic teaching until the first quarter of the fifteenth century (1423)" (Jaggi 2000:35).

the historians that medical service was one of the important programmes of the Buddhist missionaries and similarly during the Mauryan period, the Great Asoka (3rd Century B.C) championed the cause of the medical services and established a chain of hospitals and dispensaries all over the country. Later on the story of the development of hospitals and public health services in India has received considerable attention, dating back from the time of Chandragupta's and Harsha's charitable dispensaries in Pataliputra, to which the poor and destitute used to go. There were dispensaries in the Deccan during the Pallava period (AD 574-879) and in the South during the Chola period (AD 900-1200) (Jaggi 2000: xiv).

During the ancient times in India, Medical education was carried out in the following procedures: learning art and medicine from a teacher as his apprentice; or joining *gurukula,* a residential school situated in the forests away form crowded habitations; or enrollment as an understudy at the University of Taxila,[5] or Kasi (Varanasi) or Nalanda (Jaggi 2000: 30 and Sharma 1991:7).

Then followed a long period of medieval history marked by unsettled political conditions and several invasions from outside under which several new systems of TM such as Unani (13th Century) and Homeopathy (18th Century) were introduced in India and gained importance too. However, form 18th Century, gradually the patronage for these medicines was decreased (CCRUM 2006:3). Especially during the British rule in India, its growth was stunted, its teaching and training were stopped from being spread and its monopoly in practice or utilization was eroded greatly by the officially supported systems. Some even say that the ignorance and indifference prevailing among the members of the medical profession in general and of the medical teachers in particular concerning the long and rich heritage of India, in matters of Public Health and Medicine,

[5] Taxila situated 20 miles west of Rawalpindi (now in Pakistan), was the most important seat of learning in ancient India, dating from the sixth century BC. It attracted students from all corners of India and also form abroad: Rajagriha, Mithila, Kasi, Ujjain, Kuru, Koshala, etc. Some of the most learned men in ancient India are said to have either graduated form Taxila or been associated with it. These included Atreya, Chanakya (Kautilya), Panini, Jivaka, Jyadu, Kumaralabdha, Ashvaghosa, Seva, Nagarjuna, etc. Vincent smith says in his history, "it was the leading seat of Hindu learning where crowds of pupils form all quarters were taught the three Vedas and the eighteen accomplishments... the medical school there enjoyed a special reputation..." (Jaggi 2000: 31).

is partly due to the type of education they got under the British rule and later under the same pattern of education, followed by India, even after Independence.

The British Medical Policy in India gave more importance for the propagation of the western medicine and has suppressed the Indian Systems of Medicine.[6] As a result Ayurveda barely survived because of its native roots and also because the official systems of medicine could not reach everywhere particularly in the rural areas.

However after India got independence, the government has expressed serious concerns about the development of the Indian systems of Medicine and getting it back into the National Health Care Systems of the Country which has reflected in the adoption of various legislations concerning the Indian systems of Medicine. Simultaneously, initiatives to develop Homoeopathy were also taken because during the beginning of the 20th century it continued to spread in India. The popularity of the system led to a mushroom growth of quacks practicing Homoeopathy. Seeing this deplorable state of affairs, efforts were made by the Government. It took several steps and in 1948, a Homoeopathic Enquiry Committee was set up to evolve a suitable arrangement to regulate teaching and practice of Homeopathy. The setting up of Homoeopathic Enquiry Committee in 1948, Committee by Planning Commission in 1951 and the Homoeopathic Pharmacopoeia Committee in 1962. The Homoeopathic Advisory Committee which was set up 1952 by the Govt. of India testified the government's intention of developing

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[6] A best example of this is the Medical Educational Systems during the British Rule. The earliest definite regulations on the medical education were those issued in the General order of June 15, 1812, directing the training of European and Eurasian boys to form a Sub-Medical Service for the army. Indians however were not admitted to this class. Calcutta was naturally the seat of the early development of allopathic medicine in India under the British influence. After the middle of the eighteenth century, the British surgeons, in charge of hospitals trained a few Indians in the general aspects of diseases and in European modes of treatment. At first, instruction was in Urdu or Sanskrit for a very short period. Later on in the General Order of January 28, 1835, the then Governor-General of India, Lord William Bentick, has passed resolutions (based on the report of committee established in 1833 for the purpose of "improving the constitution and extending the benefits of the Native Medical Institutions, and suggesting a system of management and education calculated to give effect in both of these respects to the wishes of the Government") for the abolition of the Native Medical Institutions and English was made the compulsory medium of instruction which lead to the establishment of first medical colleges in India at Calcutta, Madras and Bombay, etc. One of the crucial provisions of the resolutions which was deliberately included to suppress the ancient Indian Medicine was that, "all the pupils be required to learn the principles and practice of medical science in strict accordance with the mode adopted in Europe". This was the main step authoritatively taken by the British Empire to promote the western medicine in India. Historians say that there were hardly any instances where the British has encouraged or promoted the ancient Indian medicine, rather it suppressed it by all possible means.

homoeopathic medicine in India. At the instance of the recommendation of these Committees, the Government of India has accepted Homoeopathy as one of the national system of medicine and started releasing funds for its development, during the Second Five-Year Plan. Some of the States also made their own contribution to Homoeopathic Education, the employment of homoeopathic practitioners in health services and regulating the practice by enacting States Acts & Rules, etc. Eleven years later the recommendations of these Committees led to the passing of the Homoeopathy Central Council Act in 1973 for the regulation of the medical education in Homoeopathy and for the maintenance of the national registrar of the homoeopathic medical practitioners in India. Homoeopathy now has been accepted as one of the National Systems of Medicine in India.[7]

In the field of Unani medicine, Unani Pharmacopoeia Committee was constituted by the Government of India in 1964, consisting of Unani experts and scientist with a view to maintain uniformity in the standards of drugs and to prescribe standards for compound formulations and also to prescribe tests for identity, purity, efficacy and quality of the drugs. Pharmacopoeial Laboratory of Indian Medicine at Ghaziabad was also established under the Govt. of India to workout standards and drug testing for ISMs at national level.[8] India has also taken steps for promoting Yoga and Naturopathy in the western countries too.

Based on the above description of the status of ISMs in the ancient and the British rule and the efforts to bring them to the main stream of the health care services, now it is required to examine the domestic legislations which regulate the Indian Systems of Medicine in terms of promotion, development and protection. The following part of this chapter first attempts to analyze the legal status of the Indian Systems of Medicine under the Indian Legislations followed by a critical analysis of the legislations and efforts taken

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[7] Article 2(e) of the IMCC Act, 1970 recognizes Homoeopathy as one of the India system of medicine. Homeopathy now in India enjoys Government support along with the other systems of medicine because Government is of the view that presence of all these complementary and alternative systems of therapeutics offers a much wider spectrum of curative medicine than is available in any other country.

[8] Unani Pharmacopoeia Committee (UPC) consists of expert physicians, scientists, botanists, pharmacognocists, chemists, manufacturers and experts of medicine. The first committee was constituted in 1964 for three years. Every third year it is being re-constituted. Drug Technical Advisory Board constituted for Ayurveda, Unani & Siddha under the Drugs & Cosmetics Act & Rules-1940 to control the standards of drugs, manufacturing, sales & distribution of Unani drugs. PLIM is a Government Drug Testing Lab for standardization and quality control of Ayurveda and Unani drugs.

by the Government of India with regard to the protection of Traditional Medicine or the Indian Systems of Medicine in response to the rampant challenges of biopiracy.

IV.3. Regulation of the Indian Systems of Medicine: Existing Legal Framework

a) The Drugs and Cosmetics Act, 1940

Provisions relating to the Ayurveda, Sidha and Unani Medicines drugs were included in the Act, through an amendment in 1962 (Chapter IV A) which came into effect in 1969. The Act provided for the establishment of the Ayurveda, Sidha and Unani Drugs Technical Advisory Board in 1969, to advise the Central Government and the State Governments on technical matters regarding the regulation of manufacture and sale of drugs on a commercial scale [Section 33EEB]. However, the Act does not govern the *Vaids* and *Hakeems* who manufacture drugs of Ayurveda or Sidha or Unani for their patients and also for the manufacture of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis [Section 33EEC].

The Ayurvedic, Siddha and Unani Drugs Consultative Committee is constituted to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs [Section 33D]. The Act lists around 54 texts of Ayurveda, 29 texts of Sidha and 13 texts of Unani Medicines which are considered as most authoritative texts in their respective fields [Schedule 1]. Later on in the rules of the Act,[9] homoeopathy was also included but no texts of this system are mentioned.

b) The Indian Medicine Central Council Act, 1970 (IMCC) and the Homeopathy Central Council Act, 1973 (HCCA).

The IMCC Act and the HCC Act were enacted to provide for the constitution of the Central Council of Indian Medicine (CCIM)[10] and the Central Council of

[9] The Drugs and Cosmetics Rules, 1945 was passed by the Central Government through *No. F. 28-10/45-H* (1) according to power conferred by the Act. Homoeopathy was included in 1969.

[10] The Central Council of Indian Medicine is the Statutory Body constituted under the Indian Medicine Central Council Act, 1970 vide Government of India Gazette Notification Extraordinary Part II Section 3(ii) dated 10.8.1971. The main objectives of the Central Council are as under:-

Homoeopathy (CCH)[11] and for the maintenance of a Central Register of Indian Medicine and Homoeopathy. Later on in 1979, these Councils were bifurcated into four research councils namely, (i) Central Council for Research in Ayurveda & Siddha (CCRAS)[12], (ii) Central Council for Research in Unani Medicine (CCRUM)[13], (iii) Central Council for Research in Homoeopathy (CCRH)[14] and (iv) Central Council for Research in Yoga

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1. To prescribe Minimum Standards of Education in Indian Medicine *viz* Ayurveda, Siddha and Unani Tibb.
2. To advise Central Government in matters relating to 'inclusion' (Recognition) and 'withdrawal' (De-recognition) of medical qualifications in Second Schedule to the Indian Medicine Central Council Act, 1970.
3. To maintain the Central Register of Indian Medicine and revise the Register from time to time.
4. To prescribe Standards of Professional Conduct, Etiquette and Code of Ethics to be observed by the practitioners. Source:www.ccimindia.org.

[11] The Central Council of Homoeopathy is a statutory Body constituted by the Government of India under the provisions of Homoeopathy Central Council Act, 1973. Its main objectives include (a) regulating the homoeopathy medical education in the country and (b) to maintain a Central Register of Homoeopathy Practitioners in the country and matters connected there with and also (c) to standardize professional conduct, etiquette and code of ethics for the practitioners of Homoeopathy. The role of the Council is to prescribe minimum standards in homoeopathic medical education in the country. The Colleges are required to satisfy these minimum standards for getting recognition from the Universities, Institutions and Boards in the country. The Central Council of Homoeopathy continues to play its role in regulating and overseeing the implementation of standards in Homoeopathic medical education in the country. To achieve its objectives, the Council monitors the minimum requirements, norms and standards by undertaking inspections of the Colleges in the country. The Council also undertakes inspections of examinations being conducted by various Universities in the country. The Central Council of Homoeopathy is supported by the Central Government through annual budget grants. During the year 2005-06 the CCH has been provided with Rs.70.00 lakhs under Non-Plan and Rs 10.00 lakhs under Plan under Budget Estimates. Source:www.ccrhindia.org

[12] The Central Council for Research in Ayurveda and Siddha is an autonomous body under Department of AYUSH, Ministry of Health & Family Welfare, Government of India set up for the formation, coordination, development and promotion of research on scientific lines in Ayurveda and Siddha. Its activities are carried out through its 38 institutes/centres/units located all over India and through a number of Units located in Universities/ Institutes/ Hospitals of Ayurveda and Siddha. The Council is also financing suitable research studies of Ayurveda, Siddha and allied sciences. The emphasis is on finding effective and low-cost remedies for various diseases through systematic research. Research activities of the Council include Clinical Research, Health Care Research, Drug Research, Literary Research and Family Welfare Research. Now the Council has also stepped into the field of Neutraceutical and Cosmaceutical research. Source: www.ccras.com

[13] The Central Council for Research in Unani Medicine was established by the Ministry of Health and Family Welfare, Government of India as an autonomous organisation in the year 1979, to initiate, aid, develop and to co-ordinate scientific research in Unani System of Medicine. The Council is engaged in the multifaceted research activities in the field of Unani medicine. The Council's research programme comprises clinical research, drug standardisation, survey and cultivation of medicinal plants and literary research. These research activities are being carried out through a network of 22 Institutes/Units functioning in different parts of the country. These include two Central Research Institutes of Unani Medicine – one each at Hyderabad and Lucknow, eight Regional Research Institutes of Unani Medicine. Source: www.unanimedicine.org

[14] The Central Council for Research in Homoeopathy is fully funded by the Government of India and is engaged in research in Homoeopathy in the country. The Council functions through a network of 40

& Naturopathy (CCRYN)[15] has continued to initiate and guide, develop and coordinate scientific research in different aspects of respective systems, both fundamental and allied. These Councils are the apex bodies for research in the concerned systems of medicine and are fully financed by the Government of India.

c) The Department of AYUSH[16]

The Department of Indian Systems of Medicines and Homoeopathy (ISM & H)[17] established in Ministry of Health and Family Welfare in March, 1995 was renamed as the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November, 2003. The Department continued to make steady progress during the year 2005-2006. Emphasis was laid on implementing the schemes which addresses the thrust areas identified by the Department, such as: upgradation of educational standards; quality control and standardization of drugs; improving the availability of raw material, research and development; and awareness generation about

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Institutes and Units located in different parts of the country. These Institutes and Units are engaged in research in various aspects of Homoeopathy such as (i) Clinical Research, (ii) Drug Proving Research, (iii) Clinical Verification Research, (iv) Drug Standardization, and (v) Survey, Collection and Cultivation of Medicinal Plants. Thrust areas (Evidence-based Research), the Council has identified the following areas for conducting Evidence-based research in Homoeopathy :

1. Fundamental and Basic Research on mechanism of action of Homoeopathic Medicines
2. Clinical trials on predefined protocols
3. Double blind randomized controlled studies (In vitro)
4. Collaborative studies with Centres of Excellence in Allied Sciences.

[15] Central Council for Research in Yoga and Naturopathy (CCRYN) is a society registered under the Societies Registration Act as an autonomous body under the Department of AYUSH, Ministry of Health & Family Welfare. The basic objective of the Council is to conduct Scientific Research in the field of Yoga and Naturopathy. However, in the absence of any other Statutory Body to look after the Education & Training in these systems, the objectives were later amended to include Education, Training and Propagational aspects of these disciplines. The National Health Policy of 1983 and also the National Policy on ISM&H -2002 envisage integration of AYUSH with the modern system of medicine. Mainstreaming of AYUSH is the core strategy envisaged under National Rural Health Mission with an objective to improve outreach and quality of health delivery in rural areas. The objective of the integration of AYUSH in the health care infrastructure is to re-enforce the existing public health care delivery system, with the use of natural, safe and friendly remedies, which are time tested, accessible and affordable. Source: www.ccryn.com

[16] See Figure 1 at p. 108

[17] Objectives of the AYUSH are: To upgrade the educational standards in the Indian Systems of Medicines and Homoeopathy colleges in the country ; To strengthen existing research institutions and ensure a time bound research programme on identified diseases for which these systems have an effective treatment; To draw up schemes for promotion, cultivation and regeneration of medicinal plants used in these systems; and to evolve Pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs (AYUSH Annual Report, 2005-2006).

the efficacy of the systems domestically and internationally. Standardization of drugs and quality control continued to receive focused attention.

The Department has been taking serious initiatives for integrating AYUSH with the modern medicine. Mainstreaming of AYUSH is envisaged in the National Rural Health Mission. AYUSH has also established the National Medicinal Plants Board (NMPB)[18] to coordinate activities relating to conservation, cultivation, marketing, export and drawing policies and strategies for the development of medicinal plants sector and a Drug Control Cell (DC Cell)[19] to deal with the matters pertaining to licensing and regulation of drugs and control of misbranded/adulterated and spurious manufacturing of Ayurvedic, Unani and Siddha Drugs and other matters.

V.4. Implementation Issues: Indian Experience

a) The Biological Diversity Act, 2002[20]

Biodiversity is a multi-disciplinary subject involving diverse activities and actions. Biodiversity encompasses the variety of all life on the earth. India is one of the 12-Mega Bio-diverse countries of the world.[21] With only 2.5% of the land area, India already accounts for 7-8% of the global recorded species. Over 46,000 species of plants and 81,000 species of animals have been recorded in the country so far by the Botanical Survey of India, and the Zoological Survey of India, respectively. India is an acknowledged centre of crop diversity, and harbours many wild relatives and breeds of domesticated animals. India is also rich in traditional and indigenous knowledge, both

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[18] NMBP till now has provided financial to the farmers for the cultivation of the 32 varieties of medicinal plants among 1500 identified medicinal plant species available in the soil (NMBP Website).

[19] The DC Cell also deals with developing Traditional Knowledge Digital Library (TKDL) and matters relating to Intellectual Property Rights (IPR) as also coordination with Government of India Ministries/Departments concerned with IPR and patent claims. Besides, Information, Education & Communication (IEC) Cell and a Facilitation Center have also been functioning in the Department.

[20] The Biological Diversity Bill was introduced in the Parliament in the year 2000 and was later on passed in the year 2002. See the 171st Report of the Law Commission of India on the Biological Diversity Bill 2000, chaired by Justice B.P. Jeevan Reddy, dated 19 January 2000. The Biological Diversity Act came into force on 1st October 2003.

[21] Biodiversity is not equally distributed all over the globe. Certain countries are characterized by high species richness and more number of endemic species. These countries are known as Mega biodiversity countries. Twelve such countries have been identified. Together, these countries harbour 60- 70% of the world's recorded biodiversity. These countries are: Brazil, Colombia, Ecuador, Peru, Mexico, Madagascar, Zaire, Australia, China, India, Indonesia and Malaysia.

codified and uncodified. In response to its obligation under the Convention on Biological Diversity, 1992, after 10 years of negotiations and discussions with all the stake holders, India has enacted a legislation called "the Biological Diversity Act in 2002".[22]

The following are the salient features of the Act: i) to regulate access to biological resources[23] of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources; and knowledge relating to biological resources; ii) to conserve and sustainable use[24] of the biological diversity;[25] iii) to respect and protect knowledge of local communities related to biodiversity; iv) to secure sharing of benefits with local people as conservers of biological resources and holders of knowledge and information relating to the use of biological resources; v) conservation and development of areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites; vi) protection and rehabilitation of threatened species; vii) involvement of institutions of state governments in the broad scheme of the implementation of the Biological Diversity Act through constitution of committees.

The Act prescribes some special provisions for the protection of TK. Among them Chapter II, regulates access to biological diversity. The Act prohibits "certain persons"[26]

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[22] India is a Party to the Convention on Biological Diversity (1992). Recognizing the sovereign rights of States to use their own biological resources, the Convention expects the parties to facilitate access to genetic resources by other Parties subject to national legislation and on mutually agreed upon terms [Article 3 and 15 of the CBD]. Article 8(j) of the Convention on Biological Diversity recognizes contributions of local and indigenous communities to the conservation and sustainable utilization of biological resources through traditional knowledge, practices and innovations and provides for equitable sharing of benefits with such people arising from the utilization of their knowledge, practices and innovations.

[23] The Act defines "biological resources" as plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material [Article 2(c)].

[24] "Sustainable use" means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form [Article 2(o)].

[25] "Biological Diversity" is defined as the "variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of ecosystems [Article 2(b)].

[26] The persons who shall be required to take the approval of the National Biodiversity Authority under Section 3(1) are the following:
(a) a person who is not a citizen of India;
(b) a citizen of India, who is a non-resident as defined in clause (30) of Section 2 of the Income-tax Act, 1961 (43 of 1961);
(c) a body corporate, association or organization--

from obtaining any biological resources occurring in India or knowledge associated there to for research or for commercial utilization[27] or for bio-safety and bio-utilisation.[28] The Act prevents any person from transferring the results of any research for monitory consideration or other wise to such certain persons without a previous approval of the National Biodiversity Authority (NBA) [Article 3, 4].

Article 6[29] is the important provision relating to the intellectual property rights in the Act. Though the article prevents from applying for the IPR protection "in or outside" India for any invention based on any research or information on biological resources obtained from India without prior approval of NBA, it does not prevent any person from applying for an IPR protection for any invention based on the biological resources of other countries. This provision is some thing similar to that of the Section 102 of the US Patent Law, which is giving a scope to the misappropriation of the knowledge of other countries. So also the term "may" in Sub-section 2 of the Section 6 of the Act connotes

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(i) not incorporated or registered in India; or

(ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management [Article 3(2)].

[27] "Commercial utilization" means end uses of biological resources for commercial utilisation such as drugs, industrial enzymes, food flavors, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and lives through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping [Article 2(f)].

[28] "bio-survey and bio-utilisation" means survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorization and bioassay [Article 2(d)].

[29] Article 6 reads as: "Application for intellectual property rights not to be made without approval of National Biodiversity Authority.-

(1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned:

Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

(4) Where any right is granted under law referred to in sub-section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

that it is not mandatory for the NBA to impose the conditions of sharing of financial benefits arising out of the IPR protection on any claimed invention originated form the biological resources or its connected knowledge of India. In a way this loophole in the Act, would possibly promote the appropriation of the TK without paying any royalty to the actual holders of that knowledge. The only favour the Act has done in this chapter for the benefit of the TK holders is that it does not require the local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*, who have been practicing indigenous medicine to take prior approval from the NBA for the access to the biological resources.

The Act provides for the establishment of a three tiered institutional structure at the national, state and local level.[30] The National Biodiversity Authority (NBA) established according to Chapter III of the Act, is conferred with the discretionary power of granting approval for any application of access to the biological resources for research or commercial utilisation or for the application of IPR protection for any invention based on the biological resources or knowledge originated from India [Article 18].[31] However, the Act does not mandate the Authority for taking measures necessary to oppose the grant of intellectual property rights in any country outside India, thereby making the way of misappropriation of the knowledge easier, which is another serious flaw in the Act.

The reason for this assumption is that, firstly, most of the Indian traditional knowledge holders are illiterate and generally reside in the rural areas far from the reach of the information systems. In the current age of information where everything is done in short time, these TK holding communities hardly will be aware of any patent application filed or already granted for an invention, which is based on their knowledge. Secondly, cost factor of opposing these patent applications. India had to spend several million dollars to fight just one case of Turmeric. A common man of a developing country like India, who is still striving for his daily bread and butter cannot even imagine of spending such a high amount of money for opposing an IPR granted for an invention which is based on his knowledge.

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[30] See Figure 2 at p. 109.

[31] Article 8 of the Act provides for the establishment of the NBA with its head office situated at Chennai consisting of a Chairman and ten ex-officio members representing various Ministries connected with the environment and forest and biological diversity etc. appointed by the Central Government of India. Hereinafter the NBA will be referred as "the Authority or NBA".

The Act in a way can be described as a "toothless sword", because on the one hand it makes it discretionary for the authority to grant or not to grant an approval for any application of access and IPR protection for the biological resources and the knowledge based on it and on the other it does not make it compulsory for the imposition of the payment of royalties and sharing of the financial benefits arising out of the commercial utilisation of the biological resources and knowledge of the communities – actual holders of TK.

The Act provides that "[t]he Central Government shall endeavour to respect and protect the knowledge of local people relating to biological diversity, as recommended by the National Biodiversity Authority through such measures (*in situ* and *ex situ* conservation systems), which may include registration of such knowledge at the local, State or National levels, and other measures for protection, including *sui generis* system" [Article 36(5) emphasis added] and for the constitution of a Biodiversity Management Committee within its local area "for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated sks and breeds of animals and micro-organisms and chronicling of knowledge relating to biological diversity" [Article 41]. The most disturbing fact about the Act is that all the important provisions which are concerned with the protection of TK are more recommendatory in nature rather mandatory, because this would obviously widen the space for the misappropriation of the knowledge based on the biological resources of the country and in a way would defeat the main objectives of the Act itself.

Coming to the NBA- on how effectively it has been working since establishment, till now apart from constituting seventeen State Biodiversity Boards at different states,[32] it is still engaged in assimilating the infrastructure and resources to function. Though there were some discussions on the preparations of the guidelines for the access to

[32] Chapter VI of the Act [Sections 22-25] provides for the establishment of the SBB's by the State governments through an official notification issued in the official gazette. Till now, the state governments of the following states have issued notifications of constituting SBBs in their respective states. They are: Andhra Pradesh, Arunachal Pradesh, Chhattisgarh, Goa, Gujarat, Haryana, Himachal Pradesh, Karnataka, Kerala, Madhya Pradesh, Manipur, Mizoram, Nagaland, Punjab, Sikkim, Uttarakhand, and West Bengal.

biological resources and the percentage of benefit sharing, nothing constructive has been done till date (NBA Annual Report 2004-05).[33]

b) The Patents (Amendment) Act, 2005

With the adoption of the WTO-TRIPS Agreement in 1995, India has to amend its patent laws to fulfill its obligations under the TRIPS Agreement. Accordingly, in 2005 India has enacted the Patents (Amendment) Act and introduced the product patents to food, medicines and drugs from the year 2005. The important provisions relating to the TK are: Firstly, the changes made to the definition of the term "patent" which means a patent granted for an invention under the this Act [Section 2(1)(m)] and specifications of "invention"[34] which are not patentable in Section 3 of the Act which states that "a mere new use for a known substance" [Section 3(d)] and "an invention which, in effect, is traditional knowledge or which is and aggregation or duplication or known properties of traditionally known component or components" [Section 3(p)] will not be an invention.

Secondly, the inclusion of the new provisions of patent opposition proceedings which can be done on limited grounds provided in section 25(1) of the Act as follows:

> Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground of-
> a) patentability including novelty, inventive step and industrial applicability, or
> b) non-disclosure or wrongful disclosure mentioning in complete specification, source and geographical origin of biological material used in the invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere.

Thirdly, the inclusion of the provision for the opposition of a complete patent specification of an invention which was publicly known or publicly used in India before the priority date of that claim [Section 25(3)(d)].[35]

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[33] The observation is according to the Annual Report of the NBA 2005-2006.

[34] The term "invention" is defined in Section 2(j) as "a new product or process involving an inventive step and capable of industrial application".

[35] Section 25(3): At any time after the grant of patent but before the expiry if a period of one year from the date of publication of grant of a patent ,any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds:
(d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.

The reason for the inclusion of all the above provisions is to defy the challenges of misappropriation of the TK which is already in the public domain of India or its use is known to the Indian communities or individuals from the time immemorial. One inference can be drawn from these provisions that all of them are *defensive* in nature, which can help to oppose the patents granted for the inventions whose source and geographical origin of biological material used or the knowledge, oral or otherwise is available within any local or indigenous community in India or elsewhere. Benefit sharing is not the concern of the Act.

But one doubt arises that, which type of TK knowledge is protected under these provisions? Whether it is the knowledge which is already in public domain for which the owner cannot to be identified or for the knowledge or the use is known in India (within a community or sometimes only individuals)? If it provides protection for the former type of TK then it is not questionable but if it also covers the TK of the individuals and communities which is generally protected in their own traditional way, then the Act erodes the rights of these sections of people from claiming patent protection in future.[36] To clarify this confusion, the definition of the TK has to be cleared first. And this also leads to a necessity of a *sui generis* system for the protection of TK and its subsets which could be a combination of various systems of protection, i.e. patents, trade secrets, geographical indications and as cultural heritage of the nation.

c) Traditional Knowledge Digital Library (TKDL)

India has a rich traditional knowledge of ways and means practiced to treat diseases afflicting its people. This knowledge has generally been passed down by word of mouth from generation to generation. Some of them have been described in ancient classical and other literature, often inaccessible to the common man.

A number of foreign countries are evincing interest in our plants and medicinal use described in ancient texts and treatises. A number of such medicinal uses of plants are being patented by others claiming as innovation.

Explanation: for the purposes of this clause, an invention relating to a process for which a patent is granted shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only.

[36] See generally, Shiva (2003) for an understanding on this point.

Documentation of this existing knowledge, available in public domain, on various traditional systems of medicine has become imperative to safeguard the sovereignty of this traditional knowledge and to protect them from being misused in patenting on non-patentable inventions. Though this knowledge is in public domain, the Patent Office does not have a mechanism to access this information to deny patenting rights. As mentioned earlier now it is prohibited to obtain patents for all such medicinal uses which are in public domain. It is also extremely costly and time consuming to fight patents granted to others. Thus, bringing such knowledge in easily accessible format to forestall wrongful patents was thought out to be a better way out.

The TKDL is an original proprietary database, which is fully protected under national and international laws of Intellectual Property Rights. The Council of Scientific and Industrial Research (CSIR), and the Department of AYUSH are the joint owners of the TKDL database and is carried out the by the NISCIAR.

AYUSH has also undertaken an innovative approach in the form of Traditional Knowledge Resource Classification (TKRC) that enables conversion of 1,40,000 pages of information, containing 36,000 formulations described in 14 texts of Ayurveda, into patent compatible format in various languages viz. translation of Sanskrit slokas into not only Hindi but also English, French, German, Spanish, Japanese. TKDL, based on a novel way of de-codification software, allows automatic conversion of information from Sanskrit into various languages. The information includes names of plants, Ayurvedic description of diseases under their modern names and therapeutic formulations, etc. The target users of the TKDL database are primarily the Patent examiner(s) in national and regional International Patent offices worldwide, International Search authorities (ISAs) under the Patent Cooperation Treaty (PCT) of World Intellectual property Organization (WIPO). During the current year, the Traditional Knowledge Digital Library (Ayurveda) 2nd phase[37] has been initiated. Approximately 65,000 formulations will be taken up from

[37] The second phase of the Traditional Knowledge Digital Library (TKDL) project was launched. The Library will be available to International Patent Offices in five languages namely, English, German, French, Spanish and Japanese medicinal use of plants described in classical Ayurveda, Siddha, Unani texts and already in the public domain, in patent compatible format with a view to forestalling the grant of patents for claims on intellectual properties, which are neither inventions nor innovations. A meeting of Task Force on TKDL (Ayurveda) second phase was held on 12.8.2005 which reviewed the progress of

45 selected Ayurvedic books, out of which 23,000 will be transcribed after excluding the duplicate references. The activity on identification of the formulations has been initiated. So far more than 34000 formulations have been identified from the Ayurveda texts and have been checked for the duplicates. Transcription of 25000 formulations has been completed from 14 texts out of the targeted 45 texts.

TKDL work on Unani Medicine is also in progress. The transcription of target 77000 formulations which are in Urdu, Arabic and Persian languages from 42 Unani books is being carried out in the patient application format and in languages as has been done for TKDL Ayurveda. Approximately 66000 formulations have been identified, 46,000 formulations have been transcribed and 13200 formulations have been scanned from the original texts.

Traditional Knowledge Digital Library (TKDL) database on Yoga is expected to serve the objectives of not only protecting the documented knowledge from biopiracy, but also for its use for study of combinatorial therapy with Ayurveda & Unani system which could be used for positive protection of such knowledge. Eight important books which contain the bulk of Yogic Kriyas and Asanas have been identified to start the Traditional Knowledge Digital Library (TKDL) work on Yoga. Draft Task Force report and Traditional Knowledge Resource Classification (TKRC) on Yoga has been completed and has been sent to the Task Force members and other Yoga experts.

Traditional Knowledge Digital Library (TKDL) Task Force (Siddha system of medicine) has identified eight text books of Siddha systems of medicines for digitalization. The work on Traditional Knowledge Resource Classification has been completed. The transcription of Siddha formulations has been initiated. TKDL Siddha targets 10.000 formulations from 45 Tamil texts. The work has been started in the month of September 2005.

Despite of these efforts the chain of biopiracy is still expanding. The recent case of granting patent on the Practice of Yoga in a steam room raises doubt on the effectiveness of the initiatives taken by India to defy biopiracy.

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the work done so far and formulated a road map for early completion of the remaining work relating to Ayurveda, Yoga, Siddha and Unani ancient classical texts.

d) Benefit Sharing Arrangements: A case study of the "Jeevani"

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements concerning the "Jeevani" drug, which was developed by scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe[38] in Kerala, South India. "Jeevani" is a restorative, immuno-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant *arogyapaacha*, used by the Kani tribes in their traditional medicine.[39] Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribal healers, known as *Plathis*. The knowledge was divulged by three Kani tribal members to the Indian scientists who isolated 12 active compounds from *arogyapaacha*, developed the drug "Jevaani", and filed two patent applications on the drug (and another patent based on the same plant but for different use). The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations. A Trust Fund was established to share the benefits arising from the commercialization of the TK-based drug "Jevaani". The operations of the Fund with the involvement of all relevant stakeholders, as well as the sustainable harvesting of the *arogyapaacha* plant, have posed certain problems which offer lessons on the role of intellectual property rights in benefit-sharing over medicinal plant genetic resources and traditional medicinal knowledge (Wilder 2001). The questions like:

- Who is entitled to apply for and receive patent protection, the Kanis or the TIBGRI?
- What is percentage of benefits that should go to the Kanis and who decides the amount of benefits that has to be shared?
- Who is entitled to control use of the name "Jeevani" as applied to products or processes that make use of the Arogyapacha?

To answer these questions a thorough scrutiny of the probabilities of various problems has to be made while modeling the tools of protection.

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[38] The Kani tribal people are reported traditionally to be a nomadic community who live in the forests of the Thiruvananthapuram district of Kerala in south India. Their current population is estimated to be approximately 18,000 and most of them are well settled now for a long time.

[39] See for detailed study on the case in Pushpangadhan (2005) and Wilder (2001).

V.5. Conclusion

Based on the above analysis of the regulation TM in India during various periods, one can come to conclusion that, India has a long history of practicing medicine which dates back to the very existence of the civilization. And the evidences of this assumption are the ancient texts available on the Indian Systems of Medicine especially on Ayurveda. In the ancient days, Ayurveda was the main health care system of the country. The inscriptions of Ayurvedic medicine and usage of plants on the structure of various civilizations shows the importance of Ayurveda in the health care systems. It was also treated as a noble profession, as is still treated which can be inferred with a famous Sanskrit proverb: "*Vaidyo Narayanau Hari...*" which means that a doctor or a medical professional is equivalent to the *Lord Vishnu*. This also infers the role of the Hindu religion in the health care systems of India. Ayurveda was usually taught in the *Gurukulas*, and only Brahmins were allowed to take admission in the *Gurukulas*. Till the modern period Ayurveda remained as the primary health care system of the country. Even during the Mughal dynasty also, Ayurveda continued to flourish and maintain its glory in the national health systems at par with the Unani Medicine introduced by the Mughal rulers. This situation has changed with the establishment of the British Empire in India. The British introduced the western medicine in India first on the pretext of treating their military personal who were suffering from epidemics during 1780s. Then after, they have established the medical colleges in the main cities of India where the Britishers had hold at that point of time. In the early 1820s, the Empire introduced its medical education policy wherein the first step to suppress the Indian Systems of Medicine were taken. The Britishers continued this attitude by making the teaching of the allopathic medicine as compulsory in all medical colleges and making only these degrees recognizable. The medical professionals qualified with the allopathic medicine were only allowed to enter the Indian Medical Services. This has greatly affected the practice of Ayurveda in India. Education and practice of this system along with the other Indian Systems of Medicine hardly survived during the British rule.

However, efforts were made to get back the ISMs into the National health care systems but have gained momentum only after India's independence. The constitution of various committees and enactment of various laws on the development of the ISMs was a

positive move on the Government part which has mainly focused on the upliftment of these systems of medicine. But, the problem of misappropriation which India is currently facing was never anticipated. The practice of medicine in the ancient times especially Ayurveda right from its evolution shows that monetary benefits (as the current IP regime grants to the innovators) were never the concerns of the Ayurvedic medical practitioners. *Vaids* were treated as the messengers of the gods to treat the mental and physical illness of the human beings and hence their knowledge was treated to be sacred and was protected in a way of secret. It used to be a generally accepted rule that only the government authorized *Vaids* can practice the medicine and not any others. So, one can say that the TM in India was practiced and protected in a traditional way according to the religious beliefs and social conditions of the country.

However the system has changed with the advent of the new intellectual property regime into the Indian legal system, in the creation of which India did not had any role to play.[40] It was only after the "turmeric" case, the Indian government has awakened and voiced for the protection of TK of India. These concerns of India have reflected in the Indian negotiations on the subject at the international and national fora. The enactment of the Biological Diversity Act, 2002 and the Patents (Amendment) Act, 2005 can be described as meaningful (incomplete) efforts with many uncertainties. The Acts need to clarify many important issues which will be discussed in the next chapter.

[40] For a better understanding on the response of India along with the other Afro Asian States to the existing intellectual property regime, see generally Hegde (2007).

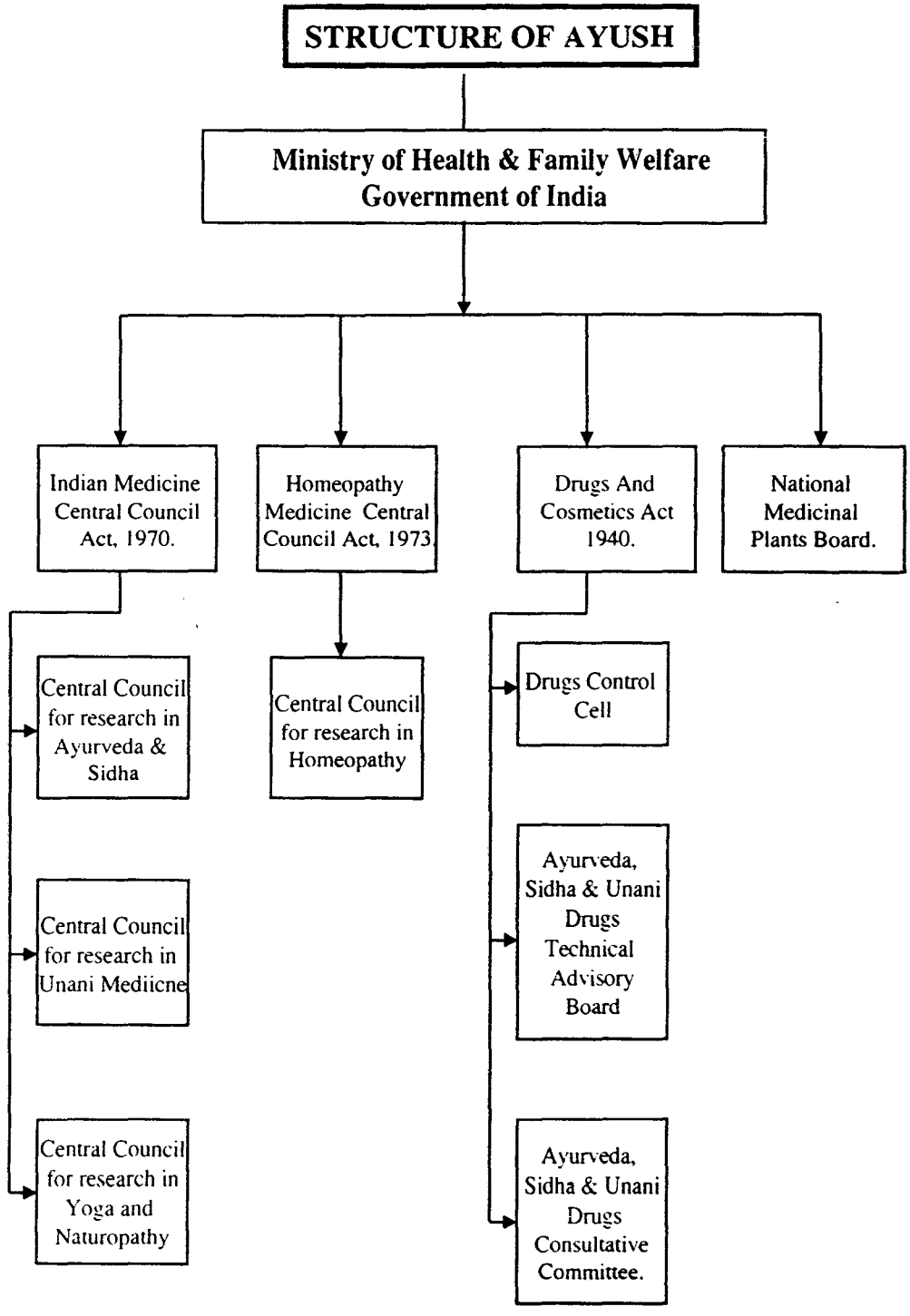
STRUCTURE OF AYUSH
Ministry of Health & Family Welfare
Government of India
Indian Medicine Central Council Act, 1970.
Homeopathy Medicine Central Council Act, 1973.
Drugs And Cosmetics Act 1940.
National Medicinal Plants Board.
Central Council for research in Ayurveda & Sidha
Central Council for research in Homeopathy
Drugs Control Cell
Central Council for research in Unani Mediicne
Ayurveda, Sidha & Unani Drugs Technical Advisory Board
Central Council for research in Yoga and Naturopathy
Ayurveda, Sidha & Unani Drugs Consultative Committee.

Figure: 1

INSTITUTIONAL MECHANISMS FOR CONSERVATRION OF BIOLOGICAL DIVERSITY & PROTECTION OF TK IN INDIA

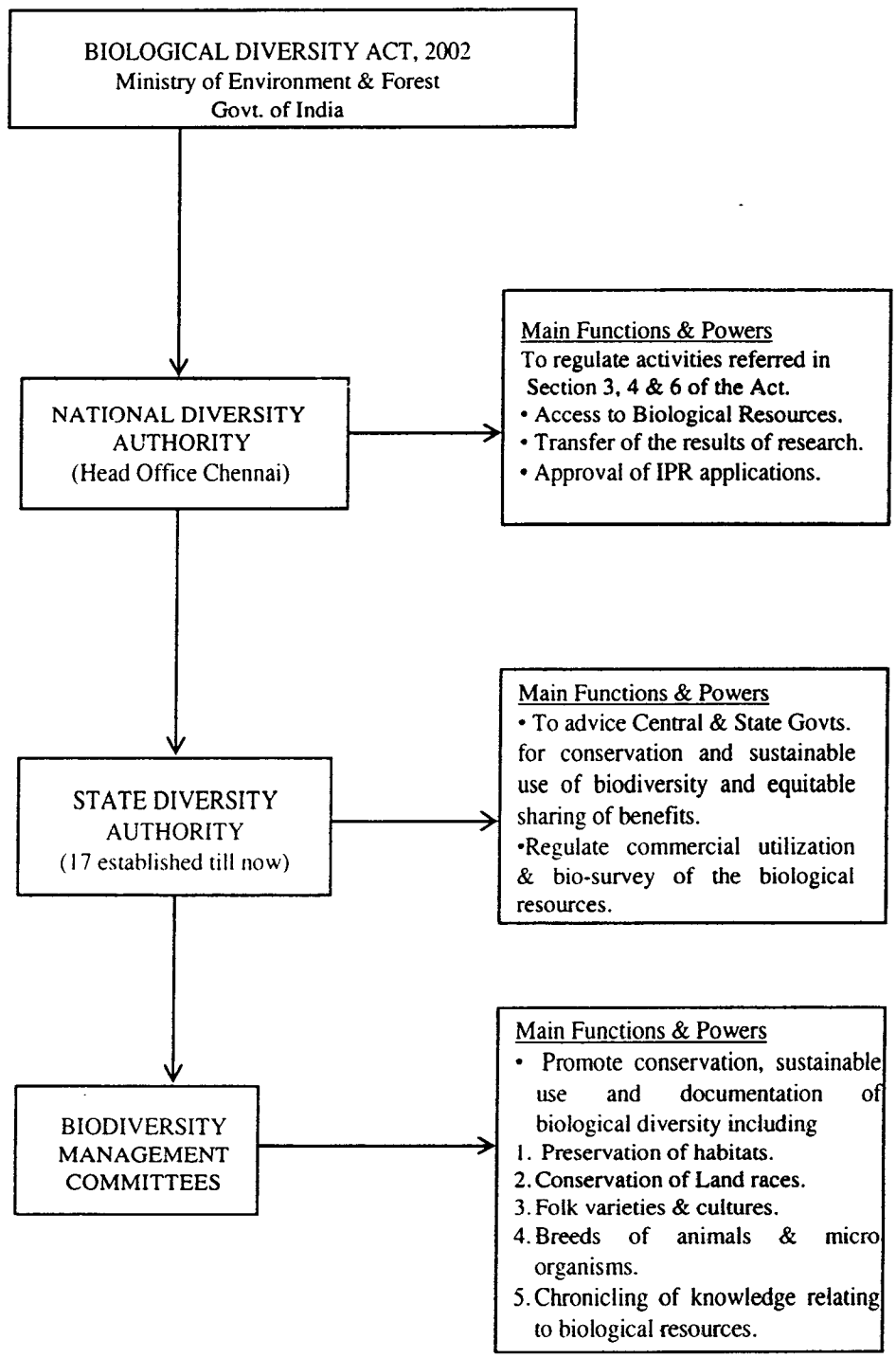

Figure: 2

CONCLUSION

CHAPTER VI

CONCLUSION

Traditional Medicine (TM) is regarded as a subset of traditional knowledge (TK). TK is a complex set of local communitarian knowledge which is not amenable to precise definition. It may be understood simply as an accumulation of local wisdom transmitted from generation to generation in a trial-and-error process allowing for sustainable adaptations to local life, culture and environmental conditions. Whilst a number of definitions for TK have been put forward, none of them have been able to capture meaningfully its essence. However, TK has been described as, "the body of knowledge built by a group of people through generations living in close contact with nature or tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields which have generally been transmitted from generation to generation, sometimes written and sometimes in oral form pertaining to a particular people or its territory and, are constantly evolving in response to a changing environment that is vital for conservation and sustainable use of biological resources which is of socio-economic value and not limited to any specific technical field, and may include agricultural, environmental, healthcare and medical knowledge, knowledge associated with genetic resources or other components of biological diversity, and know-how of traditional architecture and construction technologies".

TM, *inter alia*, refers to diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral-based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being. It has been further defined as the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, and improvement of treatment of physical and mental illness, which includes materials, processes and methods of treatment, individually or collectively held, constituted by old and recently developed knowledge, largely but not totally disclosed either in written or oral form. It has been noted that TM is also capable of commercial application in the context of modern pharmaceutical sector.

TM has several terminological and territorial identities located in different cultures. Accordingly, it is often referred by other related terms such as: complementary or alternative medicine; traditional medicinal knowledge; herbal medicine; indigenous medicine or folk medicine or tribal medicine, and so on. Different kinds of TM include traditional Chinese medicine, Tibetan medicine, chiropractic, osteopathy, Indian systems of medicine such as Ayurveda, Yoga, Unani, Sidha, Homeopathy, Naturopathy and tribal medicine known from its geographical origin.

Considering TM/TK's increasing commercial applicability attempts are made to bring them within the ambit of intellectual property protection. In this context both are characterized as "the knowledge which is generated, preserved and transmitted in a traditional context, which may be expressed formally or informally by customary law or practices distinctively associated with the traditional or indigenous culture or a community which preserves and transmits it between generations and linked to a local or indigenous community through a sense of custodianship, guardianship or cultural responsibility such as a sense of obligation to preserve the knowledge or a sense that - permitting misappropriation or demeaning usage would be harmful or offensive". The term 'knowledge' is understood in the sense that it has originated from the intellectual activity in a wide range of social, cultural, environmental and technological context which can be identified by the source of the knowledge in question (WIPO/GRTKF/IC/6/4, paragraph 58) and it is "traditional" because of the way it was acquired, used and transmitted and does not necessarily mean that it is old.

TM continues to be a key factor in health care and serves the health needs of a vast majority of people in developing countries. The World Health Organization (WHO) points out that, in Africa up to 80 per cent of the population use TM to meet health care needs (WHO-TMS 2002:1). In Asia and Latin America, 80 and 60 per cent of the populations respectively continue to use TM as a result of historical circumstances and cultural beliefs which come around. TM becomes the only affordable treatment available to poor people where access to modern health care services and medicine is limited for various economic, social and cultural reasons. According to the WHO, TM serves the health needs of almost 80 per cent of people in the developing countries, where access to "modern" health services and medicine is limited by economic and cultural reasons.

Accessibility and affordability are the two key elements of TM in developing countries. TM is some times the only affordable source of health care – especially for the world's poorest patients, also in these countries the consumption of TM is considerably more than the modern medicine/allopathic medicine. Studies also show that most of the Africans living with HIV/AIDS use traditional herbal medicines to obtain symptomatic relief and to manage opportunistic infections. Surveys and reports show that TM has the potential to provide health care at a very low price compared to allopathic medicine. An increasing section of people in developed countries now appear to prefer TM/CAM to allopathic for reasons such as lower expense, fewer side effects and higher reliability.

In response to these growing demands and considering its commercial potential, the western pharmaceutical and research institutes are now engaged in collecting medicinal plants used for various TMs worldwide and then isolating the molecules responsible for the medicinal characteristics and finally coming out with a "new" patented drug for introducing them back into the markets of developing countries at highly unaffordable prices. This calculated manipulation of TM and its features has been termed as "biopiracy". A popular view about this controversy is that "while the West has always accused the east for "intellectual piracy", the East is now facing the flight of their biological, scientific and cultural assets to the developed countries. Intellectual Property Rights are being used as a tool to legitimize this "flight" of biological and other related material.

Biopiracy has emerged as a term to describe the ways developed world take away the genetic resources and TK of the developing countries for commercial application. It has been described as "the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized countries". In simple terms, biopiracy is understood as the appropriation of the knowledge which is in the public domain and mostly held by the indigenous and local communities by individuals or institutions located outside these systems seeking exclusive monopoly control (usually patents) over these resources and knowledge. Biopiracy has an intrinsic link with IPRs. In other words, IPRs are employed as a tool to legitimize the fruits of TK/TM. Biopiracy can be committed in many ways; for example, when patents are granted for the

inventions that are neither novel nor inventive and having their origin in traditional knowledge (TK) that are already in public domain.

Biopiracy, in effect, drains the knowledge sources of the developing countries without actually acknowledging the sources. These issues need examination briefly. Firstly, the knowledge is misappropriated because the drug for which a patent is claimed or granted is not an invention for the reason that the use of such medicine is already known and hence the inventive step which is required for an invention to be patented is not satisfied. So also, the requirement of non-obviousness is not satisfied. Though the TRIPS Agreement sets these minimum standards of patentability, the patentable subject matter is determined by the national legislations. States continue to determine the subject matter of patentability in accordance with their national interests by using the flexibility to adjust national systems to national requirements (WIPO 2006:8). However, there are now efforts underway to harmonize the national laws on patents.

Secondly, TM offers health care at a very nominal cost, whereas the patented drugs are available usually at high, unaffordable prices. The patenting of TMs raises the issue of access to medicine. These medicines which are freely available to the rural populations will not be affordable if they are brought within the purview of IPR regime.

Thirdly, TM is patented neither by taking consent nor sharing the monetary benefits with the holders or creators of the TM. The other reasons are the extinction of the biological diversity which is a valuable attribute of the developing countries, and the destruction of the traditional lifestyles of the indigenous communities. The knowledge systems of these communities will be taken away from their habitat once it is patented for a third party. All these factors including the increasing number of biopiracy cases have highlighted the need to protect TK systems and have compelled the international community especially the developing countries to find ways of protecting them through an international instrument.

Developing counties therefore have formally recognized that cross-border exchange of genetic resources and TK be carried out in accordance with the principles embodied in the Convention on Biological Diversity, 1992 (CBD). According to one dominant view since pharmaceutical corporations and bioprospectors are

misappropriating it and making huge profits TK needs effective protection. According to another view, "what is worth copying is prima facie worth protecting". Secondly, besides defying biopiracy, there are still other reasons to protect TK such as to pass on the benefits to TK holders and communities. Alternatively, there is an emerging view that since TK has wider economic potential, it needs to be encouraged and conserved. Thirdly, it is believed that the conservation, preservation and promotion of the TK and TM could also contribute to the economic well-being of the developing countries.

There are two different strands of approaches towards the protection of TM, namely "positive" and "defensive" approaches. 'Positive' protection proposed for the protection of the TK holders include patent protection along with other intellectual property rights like geographical indications, trademarks, trade secrets, and so on. However, much emphasis is paid to the application of patent protections than to other IPRs. There is some opposition to this approach as well. It is argued that by creation of an IP regime to protect TK would lead to the removal from the public domain of a very large body of practical knowledge about the biosphere including solutions to health, agricultural and environmental problems affecting many people. The application of the IPR regime for the protection of TK and TM, as mentioned earlier, raises some legal issues. TK and TM may not satisfy the requirements of novelty, inventive step and utility. TM for instance, can be evolved daily with addition of new techniques and methods of treatment to the already existing knowledge.

The approach of 'defensive' protection, on the other hand, specifically deals with the prevention of misappropriation. This approach essentially requires the prevention of granting of patents or any IP protection to third parties other than the actual holders of TK without the prior informed consent taken from the holders of TK and agreement to share the benefits of the commercial exploitation of their knowledge. These concerns were reflected in the Decision V/16 of the Conference of Parties (COP) to the CBD , which requested parties "to support the development of registers of [TK], innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity through participatory programmes and consultations with indigenous and local communities, taking into account strengthening legislation, customary practices and traditional systems of resource

management, such as the protection of [TK] against unauthorized use" (UNEP/CBD/COP/5/16). The WIPO Intergovernmental Governmental Committee's (IGC) draft provisions for the protection of TK also contains similar provisions for the protection of TK against misappropriation which were adopted during the eight session of the Committee [Article 1 of the Draft Provisions, WIPO/GRTKF/IC/8/5, 2005]. One of the proposed effective tools of the defensive mechanisms at WIPO is through the documentation of the TK available in the developing countries. And also through a range of legal measures, including: a special law on intellectual property, including laws governing unfair competition and unjust enrichment; the law of contract; the law of civil liability, including torts and liability for compensation; criminal law; laws concerning the interests of indigenous peoples; fisheries laws and environmental laws; regimes governing access and benefit-sharing; or any other law or any combination of those laws.

On the other side, negotiations going on at the WTO are focusing on different dimensions of defensive protection. There appears to be a paradigm shift in the process of negotiations on the protection of TK and TM with the adoption of the Doha Declaration at the WTO Ministerial Conference in 2001. Para 19 of the Doha Declaration expanding the ambits of Article 27, has also mandated the TRIPS Council to review the implementation of the TRIPS Agreement, the relationship between the TRIPS and CBD and also the new developments with regard to TK, genetic resources and other related areas. In this process, during the negotiations, the developing countries have argued for the compulsory disclosure of origin, in all patent applications, of source of the genetic material and the knowledge if such invention is based on the knowledge of communities or knowledge is in the public domain. Developing Countries Group have also proposed an amendment to Article 29 [Article 29 *bis*] (WT/GC/W/564/Rev.1) in the process of the review of the TRIPS Agreement under the paragraph19 of the Doha Declaration 2001. The proposed amendment requires that "...an applicant for patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application".

In response to this proposed amendment, the developed countries have argued, that a new disclosure requirement would not help to prevent the issuance of "bad" patents that incorporate genetic resources without proper recognition of the source or access agreements. Instead, the US said that the disclosure requirement could generate burdensome procedures and additional costs on patent offices. It reiterated its support for private contract-based methods of ensuring equitable access and benefit sharing. The EU, for its part, repeated that it is interested in mandatory disclosure of the country of origin requirements, but would not support enforcement measures that include the potential revocation of patents, and would along with Switzerland prefer to amend WIPO Patent Rules to reach these objectives.

The need to have a *sui generis* law was raised by both the developed and developing country groups. However, the elements of the *sui generis* law are not made clear. What provisions a *sui generis* law should contain or on what lines a *sui generis* law should be adopted are not addressed sufficiently by either of the groups.

On the other hand, for the protection, conservation, preservation and sustainable use of the biological resources and their associated TK, increasing reliance is being placed on the Convention on Biological Diversity, 1992 (CBD). The CBD recognizes the sovereign rights of the indigenous communities embodying traditional lifestyles over their natural resources and knowledge. Recognizing the sovereign rights of States to use their own biological resources, the Convention proposes the parties to facilitate access to genetic resources by other Parties subject to national legislation and on mutually agreed upon terms (Article 3 and 15 of CBD). Article 8(j) of the CBD recognizes the contributions of local and indigenous communities to the conservation and sustainable utilization of biological resources through traditional knowledge, practices and innovations and provides for equitable sharing of benefits with such people arising from the utilization of their knowledge, practices and innovations. The convention says that "[e]ach Contracting party shall, as far as possible and as appropriate, [s]ubject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge,

innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices" [Article 8(j)].

The adoption of the United Nations Declaration on the Rights of Indigenous Peoples, 2006 refers to the protection of cultural and other resources of the indigenous people. India, however, has objections to the use of the term 'indigenous people'. Efforts were also made earlier by the UNESCO and FAO for the protection of the knowledge related to the genetic resources. The World Health Organization (WHO) has been engaged for the past three decades in promoting TM systems in the national health care systems.

At the regional level the initiatives taken by the African and Asian regional groups have, to some extent addressed the issues of protecting TK and its subsets, not only to conserve and preserve but also to prevent its misappropriation. These initiatives are in the form of guidelines and model provisions. Thus, the individual nations of these regional groups have to implement these provisions either through their national legislations or administrative mechanisms.

Despite this soft law approach, initiatives have been taken by the developing countries, especially India to give effect to and harmonize provisions of CBD and TRIPS Agreement. The Biological Diversity Act, 2002 (BDA) was enacted primarily to address the issues like access to genetic resources and associated knowledge by foreign individuals, institutions or companies, to ensure equitable sharing of benefits arising out of the use of these resources. To check biopiracy, the BDA provides that access to biological resources and associated knowledge is subject to terms and conditions, which secure equitable sharing of benefits. Further, it would be required to obtain the approval of the National Biodiversity Authority (NBA) before seeking any IPR based on biological material and associated knowledge obtained from India. However, exceptions are provided to the local people, community of the area, growers and cultivators of biodiversity and *Vaids* and *Hakims* for free access to use biological resources within India. The normally traded commodities are also exempted from the purview of the Act through a notification and the collaborative research through government-sponsored or approved institutions is exempted subject to overall policy guidelines and approval of the Central Government. The NBA – the implementing authority of the Act – has recently

finalized the guidelines on the collaborative research projects which awaiting its adoption. However, the Act has been criticized on the grounds that it is not mandatory upon the NBA to impose benefit sharing before granting approval for access to biological resources and for patent applications. And also it is at the discretion of the NBA to challenge any patents granted outside India for the knowledge known to Indian communities. Within India, according to the Patents (Amendment) Act, 2005 (PAA), no patents can be granted for the prior art – knowledge already known within India or elsewhere. Pre-grant opposition procedure is also provided under the PAA wherein one of the grounds of opposition is "prior art".

In sum, protecting TM should be based on diverse components and characteristics of the subject matter of TK and TM and after taking into account interests of the stake holders. The proposed *sui generis law* should take into account complex set of legal norms and instruments. It should be a combination of intellectual property laws containing patents, geographical indications, trademarks and trade secrets, and competition laws to restrict unfair trade practices, contract laws for the purpose of benefit sharing and informed consent, arrangement for the sharing of information regarding the availability of the TK in different countries and finally effective laws to promote, conserve, and ensure sustainable development of the knowledge systems of the communities. In conclusion, an attempt has been made hereunder to suggest few options both at the national and international levels.

a) Multilateral Context

- A protection model based on the existing patent norms may not be an entirely suitable option. Instead, more focus should be directed towards other forms of IPRs such as Geographical indications and trade secrets.
- Compulsory requirements of disclosure of origin, prior informed consent and benefit sharing in all the patent applications as proposed by the Developing Country Group could prove effective to defy biopiracy and also help in acquiring benefits to the TK holders. In addition at national level, prior informed consent and benefit sharing arrangement should be made compulsory.

- Alternatively, adoption of *sui generis* laws with a combination of IPR norms and also other contractual and anti-competition laws at both international and national level is also required.
- Countries while negotiating at the international level should essentially focus on the particular needs of the knowledge holders.
- International negotiations and national efforts should essentially pay attention to the urgent need to protect traditional medical systems from misappropriation as these have the unique potential to offer solutions for diseases like HIV/AIDS mostly prevalent in developing countries.

b) National Context

- The Biological Diversity Act should be effectively implemented and there should be enhanced cooperation between the State Biodiversity Boards (SBB), NBA and Biodiversity Management Committees (BMC).
- The role of the BMCs should be made significant for the registration, preservation and conservation of these knowledge systems.
- Steps have to be taken to conserve medicinal plants which are under the threat of extinction. And the National Medicinal Plants Board (NMPB) should be made accessible to all rural areas either through local nodal agencies or by establishing separate branches at each division or district level of every state. The amount of annual financial support given to the cultivators of the medicinal plants has to be increased and they should be provided proper marketing facilities.
- Efforts have to be made to educate the indigenous and local communities about their rights over their knowledge and about the methods to conserve and preserve the biological resources and to register their knowledge with the SBBs. For this purpose, the services of the print and electronic media can be utilized.

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