

# Intellectual Property Rights: Need for a Sui Generis Regime for Non-codified Traditional Medicine in India

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## ABSTRACT

Traditional Knowledge (TK) is a central component for the daily life of millions of people in developing countries, including India where access to “modern” health care services and medicine is limited due to economic and cultural constraints. Some TK is codified, that is, formalized in some way (eg Ayurveda) however, a great part of it is non-codified, such as, “folk”, “tribal” or “indigenous” medicine which is based on traditional beliefs, norms and practices accumulated during centuries old experiences of trial and error, and passed to successive generations through oral tradition. The protection under Intellectual Property Rights (IPRs) of traditional and indigenous knowledge has received growing attention since the adoption of the Convention on Biological Diversity (CBD) in 1992. However, the concept of Protection in case of TK is understood and interpreted in different ways by different groups; hence there exist two schools of thought-as per one belief protection essentially means to exclude the unauthorized use by third parties; whereas others regard protection as a tool to preserve traditional knowledge from uses that may erode it or negatively affect the life or culture of the communities who are in possession of such knowledge and have developed / applied it.

**Keywords:** Intellectual property rights, Traditional knowledge, Traditional medicine, Sui-generis, TKDL, Petty patents, Gene campaign, NIF, Patent.

## INTRODUCTION

Intellectual Property Rights (IPRs) are legal rights, which result from intellectual activity. These rights give statutory expression to the moral and economic rights of the innovators / creators

in their original creations. ‘Intellectual’ means something which is ‘intangible’ or something which is related to the ‘intellect’; ‘Property’ means something owned for which one enjoys the Right to Possession,

Use, etc. and the right to refrain others from using it without his / her authorization; and 'Right' means something one may legally or morally claim. IPRs with the basic principle of Contract between creator and sovereign state and Balance between rights of creator and public interest are essential to provide incentive towards various original creative endeavors of the mind by offering protection; give such creators official recognition; help them to recoup the money spent on R&D activities; create repositories of vital information; and facilitate the growth of both domestic industry and culture, and international trade through the treaties offering multilateral protection and promotion. Since the adoption of the Universal Declaration of Human Rights (UDHR) in 1948, Intellectual Property (IP) has been considered a fundamental human right for all people. Article 27 of the Declaration states that everyone has the right "to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

## TRADITIONAL MEDICINE

### Global Scenario

In the past decade there has been renewed attention and interest in the use of Traditional Medicine, globally. In India, 65% of the population in the rural areas uses *Ayurveda* and medicinal plants to help meet their primary health care needs. In China, Traditional medicine accounts for around 40% of all the health care delivered. In Chile, 71% of the population and in Columbia 40% of the population have used such medicine. In developed countries, traditional, complementary and alternative medicines are becoming more popular. At least 48% of the population in Australia, 31% in Belgium, 70% in Canada, 49% in France and 42% in the United States of America has used such medicines once<sup>1</sup>.

### Indian Scenario

In India, the health care services through the AYUSH systems of medicine are being successfully provided through a huge network of 785185 registered practitioners, 3277 hospitals, 24289 dispensaries, 8644 manufacturing units, 495 Undergraduate and 106 Post graduate colleges<sup>2</sup>.

### Economic Impact

Traditional Knowledge (TK) especially Traditional Medicine (TM) *vsr* to Ayurveda forms a central component for the daily life of millions of people living in the developing countries including India where "Ayurveda is the most ancient system of healthcare. India's share in the export of herbals is just 0.2% of the total global herbal market. So there is obviously vast scope for Indian manufacturers for entering the growing worldwide opportunity of business in Herbal Pharmaceutical field .The worldwide market of Herbal Medicines is US \$ 60 billion (WHO 2002). The World Health Organization predicts the overall automotive medicine market to reach US \$ 5 trillion by 2050".<sup>3</sup>

In many developing countries like Malaysia, the per capita consumption of TM products is more than double that of modern pharmaceuticals. TK especially Traditional Medicine (TM) also plays a significant role in developed countries, where the demand for herbal medicines has grown in recent years. The world market for herbal medicines has reached, according to one estimate, US\$43 billion, with annual growth rates of between 5 and 15%. For China, the leading country in this field, WHO estimates that TM generated income of about \$5 billion in 1999 from the international and \$ 1 billion from the domestic market. The European market in 1999 was calculated to be \$ 11.9 billion (where Germany had 38%, France 21% and United Kingdom 12%)<sup>4</sup>.

## TRADITIONAL KNOWLEDGE

Traditional Knowledge (TK) has been used for centuries by indigenous and local communities under local laws, customs and traditions. It has been transmitted and evolved from generation to generation. TK includes, for example, information on the use of biological and other materials for medical treatment, agriculture, production processes, designs, literature, music, rituals, and other techniques and arts. Mostly, TK comprises of knowledge which has been developed in the past, and which still continues to be developed. Most TK has been used for generations and in many cases collected and published by anthropologists, historians, botanists or other researchers and observers. However, TK is not static rather it evolves continuously and generates new information as a result of improvements in technology or adaptation to changing circumstances.<sup>4</sup> India is one of the nations blessed with a rich heritage of traditional medical systems and rich biodiversity to complement the herbal needs of the treatment administered by these systems.

### TK and IPRs

Public domain in the IPRs field generally includes any information not subject to IPRs or for which IPRs have expired. Thus, to the extent that TK is not covered under any of the IPRs modalities, it would belong to the public domain and be freely exploited. However, this technically correct view ignores the fact that TK may be deemed subject to customary laws that recognize other forms of ownership or possession rights. Despite the growing recognition of TK as a valuable source of knowledge, it has generally been regarded under Western intellectual property laws as information in the “public domain”, freely available for exploitation. In recent years, the misappropriation of folklore, traditional knowledge, and indigenous Practices has

become an increasingly important issue in global politics. In September 2000, the World Intellectual Property Organization (WIPO) established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which provides a forum for governments to discuss intellectual property matters concerning the access to genetic resources and benefit-sharing and the protection of traditional knowledge, innovations and creativity, and expressions of folklore.<sup>5</sup> Similar issues have been raised and discussed within the framework of the Convention on Biological Diversity and by such international intergovernmental organizations as the Food and Agriculture Organization (FAO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Educational, Scientific and Cultural Organization (UNESCO), and the World Health Organization (WHO).

In India, the Biological Diversity Bill, 2000 vide section 36 (iv) of chapter-IX provides for the protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a *sui generis* system. Also, sections 19 and 21 of chapter-V stipulate prior approval of the National Biodiversity Authority (NBA) before their access and mutual benefit sharing, respectively<sup>6</sup>. Overall, however, the main arguments for granting protection to TK include equity considerations; conservation concerns; the preservation of traditional practices and culture; the prevention of appropriation by unauthorized parties of components of TK; and promotion of its use/importance in development.

Giving a National agenda to move India on the path of economic progress Dr. R A Mashelkar, former Director General-Council for Scientific and Industrial Research (CSIR) said “*Launch an aggressive*

*Intellectual Policy, in the Government, in the institutions and in the Industry. Erase the impression of India as a country that is ducking and avoiding, to one where it is willing to aggressively face the global competition by leading with a positive Intellectual property policy. Launch a patent literacy mission. Invest heavily in both physical and intellectual infrastructure, which will meet the new challenges of generation of world-class Intellectual Property, its capture, documentation, protection, evaluation and exploitation.”<sup>7</sup>* Thus, rather than “protecting” TK in a way that limits access to it, governments may aim to promote the use of TK, complimenting this with measures to prevent misappropriation. An example of this approach is provided by Act No. 8423 (1997) of the Philippines, which aims “to accelerate the development of traditional and alternative health care” by improving the manufacture, quality control and marketing of traditional health care materials.

#### Provision of Patenting TK wsr TM

Since most of the TK is not contemporary and has been used for long periods, the novelty and/or inventive step requirements of patent protection may be difficult to meet. However, some elements of TK especially (TM) traditional medicine may be protected under patents. Patents have been granted on natural components, as well as on combinations of plants for therapeutic use. New plant products, cultivars and varieties of all species of plants may be protected under plant breeders’ rights (PBRs). Creating a provision for Petty patents can allow for protections similar to those of patents for knowledge consisting of a less-detailed inventive step, as in case of TK / TM. *In such cases, the knowledge must still meet the novelty and industrial application criteria.* The term of protection for a petty patent ranges from four to six years, which is shorter than the term for the standard patent. The petty

patent exists only in a few countries and is not mentioned in the TRIPs Agreement as a minimum standard for intellectual property protection. Petty patents may be more suitable for TM, as all TM is not typically documented in the same manner as Western science. Despite the fact that petty patents are not globally recognized as a minimal standard for intellectual property protection, some countries have enforced the mechanism as a way of protecting TM. Kenyan legislation mentions for a provision for petty patents in order to protect indigenous claims to traditional herbal medicine. In some cases, the protection of TK aims to prevent the “bio-piracy” (an act of exploiting the biodiversity and indigenous knowledge for selfish reasons without giving any due credit and / or compensation to the knowledge holders) and to ensure benefit sharing.

#### SUI-GENERIS REGIME

*Sui generis* literally means “of its own kind” and consists of a set of nationally recognized laws and ways of extending plant variety protection (PVP) other than through patents. TRIPs itself does not define what a *sui generis* system is or should be. One of the main objectives of the *sui generis* protection is that the exclusive monopoly granted by the State should enable the owners of traditional knowledge to be adequately compensated for their contribution.

#### Sui-generis regime in Thailand

Thailand has developed a comprehensive *sui generis* regime for TM. The “Thai Traditional Thai Medicinal Intelligence Act” distinguishes three different categories of “Traditional Formulations” *viz: the National Formulae* i.e. formulations given to the Nation which are crucial for human health. The Act stipulates that the ministry of Public Health has authority to announce a certain formula of traditional Thai medicine as a national formula. The commercial use of

a national formula for the production of drugs or for research and development is subject to permission from the government; *the Private Formulae* i.e. the formulations that can be freely used by the owner. Third parties must obtain permission from the owner to use the formula. The request for the registration of a private formula can be submitted by an inventor or developer of the formula; or an inheritor of the inventor or developer of such a formula. The Act grants exclusive rights by allowing the owner of the registered personal formula to use the formula for research and to sell and distribute any product developed or manufactured by using the formula. However, there are certain limitations to the exclusive rights. The rights over a registered personal formula subsist throughout the life of the owner and for a further 50 years from the date the applicant dies; *and the General formulae* i.e. the formulations which by virtue of being well known, remain free to use by anybody.

#### Sui-generis regime in Peru

The *sui generis* regime of Peru was established by Law No. 27, 811 of 2002, whose objectives are to protect TK, to promote fair and equitable distribution of benefits, to ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples, and to prevent misappropriation. The law grants indigenous peoples the right to consent to the use of TK. The law also foresees the payment of equitable compensation for the use of certain types of TK into a national Fund for Indigenous Development or directly to the TK holders.

#### Sui-generis regime in Costa Rica

The Biodiversity Law No. 7788 of Costa Rica aims at regulating access to TK. It provides for the equitable distribution to TK holders of the benefits arising from the use of TK.

#### Sui-generis regime in Portugal

The objective of *sui-generis* Decree-Law No. 118, of April 20, 2002 of Portugal is the registration, conservation and legal custody of genetic resources and TK. The Law provides protection against the “commercial or industrial reproduction and/or use” of TK developed by local communities, collectively or individually.

#### SUI-GENERIS IN TRIPS

Although TRIPS does not mention UPOV (International Union for the Protection of New Varieties of Plants), several countries believe that the UPOV convention meets the requirements for a *sui generis* system. However, countries do not have to join UPOV to implement a *sui generis* system to comply with TRIPS<sup>8</sup>.

#### BIOPIRACY-INDIAN INITIATIVE

To curb the menace of bio-piracy, several developed and developing countries have agreed on the idea of documenting TK. Once published in this documentation, novelty on the disclosed information could not be claimed. Following patents on turmeric, brinjal, etc, in India, work began to prepare an easily navigable computerized database of documented TK relating to the use of medicinal and others plants (which is already under public domain) known as Traditional Knowledge Digital Library (TKDL). Such digital databases would enable Patent Offices all over the world to search and examine any prevalent use/prior art. And thereby prevent grant of such patents and bio-piracy. A Traditional Knowledge Resource Classification (TKRC) is also in the process to enable the retrieval of information on traditional knowledge in a scientific and rational manner for patent examination. The project TKDL was initiated in the year 2001.



### Traditional Knowledge Digital Library

TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented at CSIR. An interdisciplinary team of Traditional Medicine (Ayurveda, Unani, Siddha and Yoga) experts, patent examiners, IT experts, scientists and technical officers are involved in creation of TKDL for Indian Systems of Medicine. The project TKDL involves documentation of the traditional knowledge available in public domain in the form of existing literature related to Ayurveda, Unani, Siddha and Yoga, in digitized format in five international languages which are English, German, French, Japanese and Spanish.

Some well known examples of Biopiracy of Indian TK include: See fig. 1a, 1b & 1c.

In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric (Figure 1 a, b & c) in wound healing. The CSIR, India, filed a re-examination case with the US PTO challenging the patent on the grounds of existing of prior art.

Council for Scientific & Industrial Research (CSIR) argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association.

The US PTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997.

In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem (Figure 2 a & b) oil.

In 1995, a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crop, and therefore, was unpatentable. The patent granted on was Neem was revoked by the EPO in May 2000.

Rice Tec. Inc. had applied for registration of a mark “Texmati” before the UK Trade Mark Registry on the basis of its US Patent No.5, 663,484 granted by US Patent Office to Rice Tec on September 2, 1997.

Evidence from the Indian Agricultural Research Institute (IARI) Bulletin regarding Basmati rice (Figure 3 a & b) was used against claims. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. Eventually, a request for re-examination of this patent was filed on April 28, 2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims.

TKDL gives legitimacy to the existing traditional knowledge and enables protection of such information from getting patented by the fly-by-night inventors acquiring patents on India’s traditional knowledge systems. So far over 2.5 lakh formulations of Ayurveda, Siddha, Unani and Yoga have been documented into the TKDL on over 34 million pages of information, over a period of more than 9 years at an estimated cost of over Rs 7 crores. During the process, traditional formulations from 259 books (151 books on Ayurveda; 33 books on Unani; 137 books on

Siddha; and 38 books on Yoga) have been transcribed.

India is signing agreements with other Patent offices for access to the TKDL database. These agreements are enabling search by international patent offices to prevent bio-piracy of India's traditional knowledge. TKDL has signed Access Agreements with several International Patent Office's like European Patent Office (EPO) in February 2009; Indian Patent Office (CGPDTM) in July 2009; German patent and Trademark Office (DPMA) in October 2009; United States Patent and Trademark Office (USPTO) in November 2009; United Kingdom Patent and Trademark Office in February 2010; Canadian Intellectual Property Office (CIPO) in September 2010; Intellectual Property Office- Australia in January 2011; and Japan Patent Office (JPO) in April 2013.

As a result of providing this access numerous attempts of patenting the traditional Indian medicine treasure could be foiled as nearly 600 cases of misappropriation were identified at various Intellectual Property Offices at application stage till 2010 (more than 200 in the EPO, nearly 200 cases in USPTO, nearly 50 cases in the IP Australia, and more than 100 cases in CIPO)<sup>9</sup>.

### Gene Campaign

'Gene Campaign' is another such project that was initiated in India in 1993 to impede the consideration of such knowledge as "new" and, therefore, patentable in some jurisdictions. The NGO "Gene Campaign" working as a leading research and advocacy organization dedicated itself to the conservation of genetic resources and indigenous knowledge. Agrobiodiversity has been the major focus area of this organization. The organization played an important role in revoking the patents on Basmati Rice and Turmeric. The 'Gene Campaign' has also worked on documentation of biodiversity and

knowledge about it in possession of tribal populations namely the Mundas and Oraons of the Chota-Nagpur region of South Bihar (now part of the new state of Jharkhand); the Bhils and Bhilalas of Madhya Pradesh; the Tharus of the Terai region in the lower foothills of Uttar Pradesh; and the Mishings, Ahoms, Assamese and Tiwa of Assam in North East India. As a part of this endeavour, educated tribal youth are recruited to help document medicinal plants and related knowledge<sup>10</sup>.

### National Innovation Foundation

National Innovation Foundation (NIF), an Ahmedabad based organization is actively working in this direction by documenting the practices at the grassroots level through its dedicate Honey Bee network in an effort to protect the Traditional Wisdom and provide adequate compensation and recognition to the traditional healers. TK may be possessed by individuals (eg healing practices and rituals), by some members of a group, or be available to all the members of a group ("common knowledge"), for example with knowledge on herbal-home remedies which is held by millions of elders.

### INCREASING AWARENESS

Slowly and gradually, the people are becoming enlightened about their rights and wish to protect their heritage of traditional knowledge passed to them over generations. This is evident from the filing of the Patent Applications in the office of the CGPDTM which is seeing an upward trend: See table 1.

### NEED OF THE HOUR

The need of the hour is to develop a *sui generis regime in case of Traditional Medicine* that is, a legal regime "of its own kind" which is specifically adapted to the nature and characteristics of TM in particular and TK in general. Although this approach

has received considerable attention in the literature, little progress has been made in terms of actually implementing this kind of protection. The establishment of a *sui generis* regime poses, in fact, many complex conceptual and practical issues like definition of the subject matter of protection; requirements for protection; extent of rights to be conferred; title-holders (individuals/communities); modes of acquisition, including registration; duration and enforcement measures; etc.

The existing conventional patent law which is primarily based on the realms of novelty, inventiveness and industrial applicability is not sufficiently sensitized and does not suffice for extending effective protection to 'traditional' knowledge in developing countries. The need of the hour is to develop a suitable regime in case of IPRs for Traditional Medicine incorporating adequate measures for 'Benefit Sharing'. But at the same time it is important to maintain a balance between the protection and promotion of such heritage because stronger implementation of IPR laws in context of TM is a double edged sword<sup>12</sup> as not giving any protection would result in exploitation of the ancient wisdom without any adequate compensation and on the other hand a protection like IPRs may reduce the access to products and treatment that are essential for a large part of the developing countries' population, especially the poor. For codified systems and formulations of Traditional Medicine, the TKDL like databases are expected to play a major role in preventing bio-piracy but for the non-codified formulations of the Traditional Medicine like Folklore practices, Tribal practices, etc., there is an urgent need of innovative regulations in the form of 'Petty Patents' and a 'Sui generis' system for protection and promotion of our Traditional Knowledge accompanied with some National level programs like the initiative taken by the National Innovation

Foundation so that the potential of non-codified Traditional Medical practices can be identified, documented, standardized and optimally utilized to the benefit of the healer as well as the ailing mankind.

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**Table 1.** Status of Patent Applications during the past decade<sup>11</sup>

Year	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
<b>Filed</b>	12613	17466	24505	28940	35218	36812	34287	39400	43197
<b>Examined</b>	10709	14813	11569	14119	11751	10296	6069	11208	11031
<b>Granted</b>	2469	1911	4320	7539	15316	16061	6168	7509	4381

(Source- Annual Report of CGPDTM, 2009-10)



**Figure 1a.** Turmeric plant



**Figure 1b.** Turmeric fresh rhizomes



**Figure 1c.** Turmeric dried rhizomes



**Figure 2a.** Neem plant with flowers



**Figure 2b.** Neem plant



**Figure 3a.** Basmati rice



**Figure 3b.** Basmati rice plant