

Legal and Legislative Assistance in Favor of Folk Medicine and THPs—An Overview

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Abstract This work focuses on prevailing legislations in favor of the indigenous knowledge and folk medicines. On relooking at various existing legislative acts and policies in hand, our research revealed that the provisions and policies in respect to traditional knowledge and folk medicine are only one aspect in existing acts and no single act or policy fully devoted for it. The objective of the study is to identify the efficacy of existing intellectual property rights in favor of those who cultivated and preserved biological resources and associated traditional knowledge. The traditional knowledge is at alarming stage and now limited to very few ethnic groups and individuals due to urbanization. Looking on variant agro-climatic condition, demography and tribal culture of India, it is an important to make regional basis program and scheme for research to ascertain the efficacy of the traditional medicinal knowledge.

Keywords Traditional medical knowledge (TMK), Folk medicine, Intellectual property right (IPR), Traditional health practitioners (THP).

Introduction

India has richest genetic resources (GR) and biodi-

versity with 15 agro-climatic zones ; Eastern and Western Himalayan region, Lower middle and upper Gangetic plain region, Trans Gangetic plain region, Eastern Western Southern and Central plateau and hills, Eastern coastal plains and hills, Western coastal plains and Ghats, Gujarat plains and hills, Western dry region and Island region. The floral wealth comprises around 18,000 flowering species wherein more than 7000 are reckoned to have medicinal values and are being used in folk remedies. These species are documented in Ayurveda, Unani, Siddha and Homoeopathy (AYUSH) system of medicine. For the trade of medicinal plants, about 1178 species are surmised of which 242 species have annual consumption level more than 100 metric tons per year. The major increase in export recorded around 2865.20 Crore from the financial year 2005-06 to 2014-15 (<https://www.nmpb.nic.in>). Non-wood forest products (NWP) excluding medicinal plants generate 50 and 70% of forest and forest export revenue, respectively (Prasad et al. 1996, Tewari and Campbell 1997). The significance of indigenous medicines in primary health sector was first recognized by World Health Organization (WHO) in Alma Ata-1978 declaration (WHO/EDM/TRM/2000). Traditional medical knowledge (TMK) has played a role in identifying substances having pharmacological value useful in western medicine (<https://www.undp.org>). It is revealed from the study done by World Intellectual Property Organization (WIPO) and the United Nations Environment Program (UNEP) that the effective protection of intellectual property is a necessary condition for generating benefits, which will be subject to access and benefit sharing (ABS), but it needs additional measures like legal and technical capacities for negotiation, superintendence and commercialization the traditional

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medicine along with business canniness and sagacity. These measures are required to add-on the role of intellectual property rights (IPR) in ABS over biological resources and traditional knowledge, TK (<http://apps.who.int/medicinedocs>). WIPO and UNEP suggested that the environmental and intellectual property (IP) policy should be framed in a coordinated and mutually supportive manner. As per the 2011 census, over 16% of India's population is largely depended upon forestry resources for their nourishment and basic needs. However, with increasing urbanization and industrialization, the Indian forest coverage had fallen from 30% to around 21.3% during the current millennium. This is below the global average of 30.6% and our own national target of 33%. It was therefore crucial to promote awareness of the necessity and significance of forest management among the local communities, particularly those living in forest land. Medicinal plants (MP) have an important role in rural human viz-a-viz animal health care (Prasad and Bhatnagar 1991). Also the NWP play important role to upgrade their economic status (Campbell 1991, Malhotra et al. 1991, Tewari and Campbell 1995). The recent work of Sen and Chakraborty (2017) focuses on Revival, modernization and integration of Indian traditional herbal medicine in clinical practice.

Thus, forest and forest based products including MP has clear ecological, social and economic benefits and therefore attention should be given to the potential for conservations of forest and protection of local community rights. From the last half century, the protection and ABS has been under debate at both the international and domestic level through different forum, acts, guidelines and policies. IP refers to any tangible or intangible property or asset, which is a product of the human intellect that has commercial value and includes any literary and artistic works and symbols, names and images used in commerce (<https://istart.rajasthan.gov.in/IPR>).

For the present study, we have made data base from following items ; amendments in our constitutions, acts and policies, previous research papers, websites of various state and central government department, decision and notices issued by courts and action taken by various Non-Governmental Organization (NGO) and societies as well as by private sector.

Traditional medical knowledge

Traditional medical knowledge, for example folk medicine, is often associated with GR. Since, GR are not anthropogenic and therefore it could not be covered directly under the roof of IP protection. However, it is of subject to access and ABS regulations under international memorandum of understanding (MoU). These agreements basically provide IP protection of TMK and do not deal specifically with associated genetic resources. The 1983 International Undertaking (IU) was the first comprehensive international agreement negotiated under the Food and Agriculture Organization (FAO) of the UN which ensure that plant GR of economic and / or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes (Gupta 2004).

World Health Organization (WHO) is strongly in favor to encourage the folk medicines and herbal remedies (www.who.int/mediacentre). One such an agreement is the Doha declaration under the World Trade Organization (WTO), wherein the IP issues concerning to public health are well guided (www.wto.org). The convention on biological diversity is an annual meeting program wherein governments from all over the world participate to discuss and make guidelines for the years to come. During the 2018 UN biodiversity conference, governments all around the world were agreed for quick implementation of the Aichi Biodiversity Targets-2010 and to complete goal until 2020 through global, regional, national and subnational levels planning and actions (<https://www.cbd.int>). In light of above, three day training program on national legislation on biodiversity for government officials of South Asian Association for Regional Co-operation (SAARC) Member States was held during 29–31 August, 2012 in India. The theme of program was based mainly on environment and biodiversity related policy and legal issues: IPRs, TK and ABS.

Intellectual property rights (IPRs)

At present, there are few IPRs are operative, particularly in India ; those concern the protection of MP and THPs. We have observed that local communities

and THPs are not well learned with existing IPR and they are not aware for their rights. The legal procedure of IPR is not accessible for the indigenous community (Arihan and Ozkan 2007). The International Labor Organization stated that the legal standards for indigenous rights fail to protect the IPR of indigenous people. However, there are few IPRs and legal governing bodies existing in India. A brief discussion on legal and government policies for the health and medicine sector is given hereafter. The Patent Amendment Act-1999 reject the patent as well as revocation of the patent including wrongful disclosure or non-disclosure of the sources of origin of biological resources or knowledge in the patent application. The unlawful marketing of traditional medicine is possible to prevent under the Trade Marks Act-1999. The Copyrights (Amendments) Act-1999 indirectly dealing with the traditional medicine and is applicable to determine the right of the THPs by using the Prior Informed Consent and Prior Art concepts. Regulation of Sale and Compulsory Evidence Based Trial Bill-2006 regulate unlicensed marketing and uncontrolled sale of the traditional herbal medicines (THM). This bill brings it under the cover of being manufactured by formulation provided in the ancient texts and to provide for compulsory listing and verification of ingredients of THM and for matters connected there with and incidental there to (MGIPMRND, Rajyasabha 2006). Specific Relief Act-1963 is helpful to protect the TMK and its practitioner under the common law and also prevent the infringement of TMK ethics. The article 19 (1) and 21 of our constitution also provide constitutional protections to the THPs in India. According to this, the ethnic group and THPs have liberty to practice their occupation and trade it (Gandhi v/s Union of India 1978). The article 51-A (g) discuss protection and improvement of the natural environment including flora, fauna, demography and physiography. The Indian Patents (Amendment) Act-2002 clarify that the TK is not included in patenting. Maheswari (2011) explored the need to document the indigenous knowledge of herbal medicines to secure patenting rights of the indigenous community.

The Traditional Knowledge Digital Library (TKDL) has been established under the Council of Scientific and Industrial Research (CSIR) and Department of AYUSH. The TKDL provides patent

examiners with prior art information, in digitized format, in five international languages (English, German, French, Japanese and Spanish), so as to prevent the erroneous grant of patents. The TKDL is not open to the public and patent officers must not reveal the contents of the TKDL to any third party, in order to protect India's interest against possible misuse (<http://www.tkdil.res.in>). At the India-US Trade Policy Forum (TPF)-2014, India has asked US for work together on international treaty to protect its traditional knowledge of medicinal plants and herbs from being patented by other nations (The Economic Times 2014).

Legislative assistance for drug and cosmetic

First Indian medicine policy was introduced in 1940 by applying Drug and Cosmetic Act. After the independence, Republic government has re-looked at depth of this act which resulted in form of traditional Indian System of Medicine (ISM) in 1959 with existing Drug and Cosmetic Act-1940. Government of India (GOI) has also made the Drug and Cosmetic Rules - 1945 to exertion of the powers granted by the Drug and Cosmetic Act 1940. Following the recommendations received through various expert committees on different ISM, a chapter comprising Ayurveda, Siddha and Unani drugs was incorporated in 1940 act by applying the act of 1964. This act has been further improved and rectified in 1983, 1987, 1994 and 2002. The Central Council of Indian Medicine (CCIM) was established in the year 1970 to govern and co-ordinate ISM.

In 1995, the department of ISM and Homeopathy (ISM and H) was formed. Later on, in 2003, it renamed as the Department of Ayurveda, Yoga and Naturopathy, Unni, Sidha and Homoeopathy (AYUSH). The major objectives of AYUSH were designed to focus on education and research in subject of traditional health practices (<http://ayush.gov.in>). The GOI has issued guideline for evaluation and analysis of drugs under ISM in the years 2006 and 2008.

Sowa Rigpa is another antediluvian traditional medical system that employs a complex approach to diagnosis. In 2012, Sowa Rigpa system of medicine

has been merged in to the CCIM as per the Gazette Notification No. 2345 dated 16.12.2011 (<https://www.ccimindia.org>). The earlier ISM and H department has now been designated as the separate ministry namely AYUSH on November, 9, 2014. The objectives of AYUSH ministry are to and strengthen the educational and research standards and to frame schemes for promotion, cultivation and regeneration of medicinal plants and to evolve Pharmacopoeial standards for ISM and H drugs (ayush.gov.in).

Legislative assistance for conservation of natural resources

The Indian Forest Policy of 1988 (MoEF 1988) and the subsequent government resolution on participatory forest management (MoEF 1990) have stressed on involvement of peoples participation in management, development and protection of the forests (www.fao.org). Panchayat extension to scheduled areas (PESA) Act-1996 grants rights to tribal and forest dwellers over forest resources and their management under the joint forest management (JFM). Owing the economic potential, NWP like medicinal plants plays key role in JFM (Prasad and Bhatnagar 1991, SPWD 1992, Tiwari 2005). The study of Zutshi (1993) on JFM performed at Golera village, Udaipur, Rajasthan showed that the peoples were more active in protection rather than the plantation and recommended the necessity of JFM.

In the 1997, a non-profit autonomous body namely Quality Council of India (QCI) has been set up jointly by GOI and Indian industry (<https://www.qcin.org>). QCI has developed the registration criteria for training the THPs for improving their diagnosis skill. The Goods Registration and Protection Act-1999 provide facility to register particular geographical location from which the medicines prepared from certain genotypes (<http://www.ipindia.nic.in>). In the year 2000, the National Medicinal Plants Board (NMPB) was set up by GOI to accelerate medicinal plants sector and to develop coupled mechanism among various ministries / departments / organizations in India for better co-ordination. The NMPB was assigned job to implement and support policies / programs for conservation, cultivation, trade and export of MP. For the documentation of TK about genetic and biological

resources, the National Innovation Foundation (NIF) was set up by the Indian Department of Science and Technology in March 2000. IPR on different varieties of food grains in public, private and farmer sector have been studied by Srivastava et al. (2015).

In the year 2001, the Protection of Plant Varieties and Farmers Rights Act has been enacted in India to provide for the establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants. For this, a separate establishment namely Protection of Plant Varieties and Farmers Rights Authority India has been settled (<http://www.plantauthority.gov.in>). However, it mainly concern over foodgrains.

Rights of THPs, ethnic groups and tribes were embodied in the Biological Diversity Act (2002), the Biological Diversity Rules (2004) and the Forest Rights Act (2006). These acts provide them rights for consultation and public participation prior to any project that may affect their livelihoods, biodiversity and associated TK ; conservation and sustainable use of biodiversity ; share fairly and equitably in any benefits arising from the utilization of biodiversity. The Forest Rights Act-2006 enables individuals to gain entitlement on any forest land if they have encroached upon and been living there for a certain number of years. However, it has been observed that the many societies of NGO which are working for community benefit in forest areas were obtained illegal encroachment on forest lands due to illiteracy among local community. Also no proper awareness extends among local tribes and communities about their rights. Therefore, it is essential to provide them legal and impartial assistance from government bodies through effective public partnership initiatives. The national Biodiversity Authority was established in 2003 to implement the Biological Diversity Act 2002.

Conclusion of above discussion states that the IPR fully oriented to THPs and to conserve medicinal plants is non-existent. Above cited protocols and authorities are general in their nature and covers wide area of different agriculture and pharmacy sector. The work of Maiti et al. (2008) highlighted on the issue misappropriation of TK and TMK. As it has defined

earlier in the text that the ethnic groups or communities are referred as a group of people who share natural resources and knowledge. Within a locality, there can be healers who revitalize the use of medicinal plants and livestock keepers who care for their traditional animal breeds.

Non-governmental assistance

To improve the socio-economic status of local tribal community few NGOs, trusts and societies have also initiated considerable action to protect rights of local tribes and to conserve the forest. The Foundation for Revitalization of Local Health Traditions (FRLHT) was established in 1991. It is a registered public trust and charitable society which has been actively working for the MP conservation since 1993. The FRLHT has been designated as a National Center of Excellence for MP and Ayurveda by the Ministry of Environment and Forests and the Ministry of Health. FRLHT has established Institute of Ayurveda and Integrative Medicine (I-AIM) in 2011 and the university of Trans-Disciplinary Health Sciences and Technology (TDU), in 2014. I-AIM is committed to design and implement self-sustaining, household and community outreach programs. TDU facilitate education, research and outreach in Ayurveda-biology, clinical medicine, MP systematics, plant genomics, data sciences, local health traditions, and theoretical foundations of Ayurveda, TK informatics and manuscriptology.

In Rajasthan, Jan Jagran Vikas Samiti Udaipur run various activities for enhancing socio-economic status of local tribes through utilizing the local available natural resources. It has given status of a NGO in 1985. It has been working with different sustainable project initiatives particularly for traditional health and community development. A socio-economic initiative has also been taken by Rashtriya Guni Mission (RGM) to conserve rich and effective TMK and promote THPs. RGM was founded in 1998 in Udaipur, Rajasthan and it was legally registered under the National Trust Act 1882. Under the RGM activities, the tremendous works have been done to strengthen the THPs, encourage communities towards traditional health systems, conserve medicinal plants, and promote and create awareness in the commu-

nity about TMK (<http://www.gunimission.org>). In Udaipur, another NGO namely Seva Mandir is also working towards conservation of village pastures and forest lands in southern Rajasthan. Seva Mandir spread awareness about the Forest Rights Act - 2006 for the illegal encroachment of incredibly valuable forest land. As an alternative, the Forest Protection Committees (FPCs) have called for the leasing of forestland to entire communities instead of individuals. The hope was to create awareness and to draw attention of the government to address forestland issues so that an open dialogue can begin between the state and community-led FPCs.

In the discussion given above, it could be concluded that the various legal and legislative provisions are articulated in constitution of India and issued through following amendments for the tribal people, TK, heritage, traditional medicines, healers and conservation of forest. Also, there are number of research and governing intuitions are operative to take care of traditional medicine and its associate sectors. However, actual execution of these policies and actions are not seen so effective and not found publicise among local communities, ethnic groups and THPs. As it is known that the patent laws protect the individual and their invention or their secret. The TK and TMK are so sparse in its own nature and therefore it could not be possible to protect effectively under the prevailing legislations and even by amendment of the provisions of the Patent Act. Another issue has arisen due to inability of tribal people to access existing IP information which is not available in their own language and in user-friendly manner. Thus, there is a need of coupled system between local communities and agencies to provide assistance with existing acts and policies on folk medical knowledge and for their socio-economic benefits. For this, incentive base schemes could also be framed. In lack of coupled system and failure of existing IPRs to protect TMK, pharmacy companies exploit the resources and smartly encash TMK without sharing the benefit with THPs. On the other hand ethnic people themselves also do not expose and extend TMK, practices and procedure due to their belief and economic reason. For this, it is necessary to provide them socio-economic-friendly atmosphere to protect and sustain TMK.

Conclusion

The existing acts, policies and action plan in India concerning to TMK and MP are not found to be passive at ground level. The actual execution is not seen so effective on ground and not found publicise among local communities, ethnic groups and THPs. It fails to grown up socio-economic status of local community and also THPs are not recognized as a significant unit in rural health care. It has also been noted that each establishment is working independently and therefore there is a need of coupled system that work for linkage between various establishment, government, NGOs and local community. It has also been noted that the folk medicine practices by tribes is not identified as core unit in AYUSH. The TK and TMK are so sparse in its own nature and therefore it could not be possible to protect effectively under the prevailing legislations and even by amendment of the provisions of the Patent Act and IPR policy. Our work emphasized on necessity of exact legislative act or policy that only oriented for protection of folk medicines and THPs. Since India has variant agro-climatic and demography, it is therefore important to make regional basis program and scheme for research to ascertain the efficacy of TMK.

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