

TRADITIONAL KNOWLEDGE AND BIO-PIRACY IN INDIA

NAIN<u>A GUPTA</u>

ISSUE BRIEF

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ABSTRACT

In a biodiversity-rich and developing country like India, protection, preservation, and promotion of traditional knowledge becomes especially important due to its huge economic potential. This brief delves deeper into issues like bio-piracy and the existing difficulties in protecting traditional knowledge, especially that which is indigenous and collectively owned in nature. It also looks at the various institutional mechanisms in place to protect indeigenous knowledge in India, with particular emphasis on the clauses of the TRIPS agreement and the Convention on Biological Diversity or CBD and India's position on them.

INTRODUCTION

India is among the 17 mega-biodiversity¹ countries identified by Conservation International and the United Nations Environment Programme. It has at least 7-8% of the recorded plant and animal species of the world, with over 45,500 plant and 91,200 animal species documented within the geographical boundaries of India (National Biodiversity Authority 2018). Indigenous species of plants are integral to traditional medicinal knowledge systems like Ayurveda, Siddha, and Unani, apart from other lesser known tribal knowledge systems in the country. In fact, around 13,400 indigenous plant species are used as medicines, fodder, pesticides, resins, dyes, gums, perfumes and food by the indigenous population in India (Ibid.).

The World Intellectual Property Organization defines traditional knowledge as a "living body of knowledge passed on from generation to generation within a community. It often forms part of a people's cultural and spiritual identity" (WIPO n.d.). Traditional Knowledge encompasses technical know-hows, practices, skills, and innovations with respect to biodiversity, agriculture, ecology, science and health (Saba 2018). In India, traditional medicinal systems meet the healthcare needs of a large section of the population, with the Ministry of Ayush suggesting that 14.2 crore patients meet their healthcare needs through Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Sowa Rigpa forms of medicine (Ministry of AYUSH n.d.) (Table 1).

System	IPD	OPD			Total	
	CHC	СНС	Dispensaries	PHCs	IPD	OPD
Ayurveda	13,90,950	165,57,395	7,14,86,719	84,55,545	13,90,950	9,64,99,659
Unani	1,02,884	22,20,231	81,09,909	15,04,284	1,02,884	118,34,424
Siddha	2,10,016	106,17,115	16,34,022	1,68,58,888	2,10,016	291,10,025
Yoga	15,741	1,56,4861	50,150	12,82,064	15,741	28,97,075
Naturopathy	18,636	1,38,187	2,10,634	72,176	18,636	4,20,997
Sowa Rigpa	0	0	7,050	0	0	7,050

TABLE 1: PATIENTS AT TRADITIONAL KNOWLEDGE-BASED MEDICAL FACILITIES IN INDIA

CHC - COMMUNITY HEALTH CENTRE; PHC - PRIMARY HEALTH CENTRE SOURCE: MINISTRY OF AYUSH N.D.

¹ Countries that are home to a majority of the world's plant and animal species, particularly endemic species (existing in only one geographic region).

Also important to note is the fact that traditional knowledge has immense economic value and potential. For instance, India is the world's largest producer and exporter of turmeric with exports recorded at USD 236 million in 2018 (Centre for Advanced Trade Research 2019). The domestic trade of the AYUSH industry in India is about USD 1.2 billion, while the world trade in herbal products is currently valued at USD 120 billion and is expected to touch around USD 7 trillion by 2050 (PTI 2018). Hence, the preservation, protection and promotion of traditional knowledge-based innovations and practices of local communities is particularly important for India.

Furthermore, the issue of bio-piracy provides further impetus to review practices of protection and preservation of traditional knowledge in India. Biopiracy is the unauthorised use and patenting of genetic resources or traditional knowledge, without the permission of the countries or communities that are the rightful owners of such knowledge (World Trade Organization 2011). In spite of various international agreements, there have been cases of bio-piracy involving plants grown in India (often those with medicinal properties). Few well-known cases include Neem, Turmeric, Phyllanthus amarus, etc., where patent offices in countries like the US had granted patents on products derived from the traditional knowledge of local Indian communities (Shiva 2016).

BIO-PIRACY AND THE DIFFICULTIES IN PROTECTING TRADITIONAL KNOWLEDGE

While bio-piracy is inherently an act of appropriation of traditional knowledge by individuals and corporations for commercial gain, there are existing difficulties in protecting such knowledge that allow attempts at appropriation. These include:

1. Collective Resource: Intellectual Property Rights (IPR) provide protection to individual ownership of knowledge but traditional knowledge usually belongs to a community or a tribe who have been practising it for generations.

2. Criteria of novelty in IPR: Most traditional knowledge is not based on scientific methods of assessment and evolves organically with the help of communities as a response to new challenges and needs. The evolution of such knowledge across generations means that the novelty or innovative factor is non-existent. Thus, such knowledge fails to meet the criteria of novelty required for IPR patents.

3. Limited protection under IPR: Traditional knowledge requires protection for an indefinite period simply because it is associated with the living practices of an indigenous population. These practices may also be vulnerable to appropriation (Bijoy: 2007). At present, the Indian Patents Act does not allow for evergreening of patents.

4. Problem of benefit-sharing: When it comes to sharing monetary and other benefits after commercialisation of a traditional practice through a legal procedure, it is sometimes difficult to identify the beneficiary. For instance, in the mid-1990s, scientists at the Tropical Botanic Garden and Research Institute (TBGRI) developed and patented a drug called "Jeevani". The development of the drug borrowed heavily from the medicinal knowledge of the energising properties of Arogyapacha herb, from the Kani

tribe in Kerala. Although TBGRI ended up signing a benefit-sharing agreement with a trust with members from the Kani tribe, not all Kani people agree with the arrangement claiming traditional rights on beneficial properties of the herb (Bijoy 2007).

5. Lack of documentation: Traditional knowledge is usually a product of learning through experience and oral traditions passed over centuries. It may have been generated, transmitted, and strengthened through rituals, songs, oral history, human interactions, ceremonies, languages, experiences and practices. These traditions are often inaccessible to the patentee or the concerned authority due to the lack of formal documentation.

6. Language Barriers: Even in cases where it is documented, traditional knowledge exists in vernacular languages, which may act as a barrier when it comes to it being universally accessible.

INSTITUTIONAL EFFORTS AT PRESERVING TRADITIONAL KNOWLEDGE

Over the years there have been several national and international policies/conventions to secure the rights of source countries as well as indigenous populations over traditional knowledge.

At the national level, one such intervention is the Traditional Knowledge Digital Library (TKDL) which was created to overcome the problem of documentation and availability of information about traditional knowledge in the public domain (Tarunika and Tamilselvi 2018: 1256). TKDL is a collaborative project between the Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). It documents traditional knowledge from existing literature in a digitised format, in five international languages, viz. English, French, German, Spanish and Japanese (James 2018). It allows access to this information to patent offices around the world under an access agreement.

Although there is no specific legislation for the protection of traditional knowledge in India, the pre-existing legal framework for IPR as well as other acts provide for protection of traditional knowledge through various provisions:

1. The Indian Patents (Amendment) Act 1970: The Act has provisions for mandatory disclosure of source and geographical origin of the biological material used in the invention while applying for patents. Provisions include non-disclosure or wrongful disclosure of known traditional knowledge as grounds for opposition and for revocation of the patents, if granted.

2. The Trade Marks Act 1999: Trademarks can be used to secure protection for the Indian System of Medicine practices since the Trade Marks Act extends to services as well.

3. The Geographical Indications of Goods (Registration and Protection) Act 1999: The Act facilitates protection of collective rights of rural and indigenous communities and their traditional knowledge (Tarunika and Tamilselvi 2018: 1256).

By registering an item which is the product of traditional knowledge, as GI, it can be protected indefinitely by renewing the registration when it expires after a period of ten years.

4. Biological Diversity Act 2002 (NBD): The Act establishes a three tier institutional structure for biodiversity governance in India - National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs). The Act makes applications for IPRs of products/inventions that use traditional knowledge subject to approval by competent authorities. Under the Act, BMCs prepare People's Biodiversity Registers (PBR) in consultation with local communities. PBRs contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them.

5. Protection of Plant Varieties and Farmers Rights Act 2001 (PPVFR): Among other provisions for recognition of traditional knowledge of farmers, it stipulates benefit-sharing, recognition and reward (through a Gene Fund) for farmers engaged in the conservation of genetic resources of plants.

At the international level, measures for protection of traditional knowledge range from a mix of binding as well as non-binding agreements. The Convention on Biological Diversity (CBD) was the first move towards international dialogue on the protection of biodiversity and TK protection (Ministry of Environment, Forest and Climate Change 2019). Subsequently, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) 2007 provides indigenous peoples "the right to maintain, control, protect and develop their intellectual property over their cultural heritage, traditional knowledge, and traditional cultural expressions" (United Nations 2007: 23). Under the Declaration, states have to provide "redress through effective mechanisms...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." (12).

Additionally, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted by the FAO in 2004. Through an innovative multilateral system of access and benefit sharing, the treaty allows citizens of signatory countries to use the resources provided, as long as they use them for non-commercial purposes and that they do not acquire IP rights over such resources (Food and Agriculture Organization n.d.). However, most prominently under the World Trade Organisation (WTO), the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement as it stands does not extend protection to traditional knowledge. As a result, proponents of protection of traditional knowledge have missed a key opportunity to benefit from the effective implementation and enforcement mechanism of the WTO.

THE TRIPS DEBATE ON BIO-PIRACY

It has long been argued that in cases where traditional knowledge forms a basis for further scientific developments being sought for a patent-grant, there should be a mechanism to ensure disclosure of information (James 2018). At the moment, there is a proposal to amend the TRIPS agreement in the WTO, aiming at making it mandatory for patent applicants to disclose the origin of genetic resources, along with any traditional knowledge used in such inventions. This "disclosure of origin" would prevent wrongful patenting. It will naturally lead to evidence that the patent applicants received "prior informed consent" (a term used in the CBD), and proof of fair and equitable benefit-sharing.

However, some members have advocated for other ways of achieving these objectives without amending the TRIPS agreement and without "disclosure" (World Trade Organization 2011). These include contracts with the party considered to be the rightful owner, and traditional knowledge databases that patent examiners can use to avoid wrong patenting. A few other countries have outrightly opposed patenting of life forms, making the practice of patenting completely impossible and the issue of disclosure irrelevant.

The other debate surrounding the TRIPS agreement is particularly important for India and other developing countries because it seeks to address biopiracy directly. The main challenge with the TRIPS agreement is that it allows these biological resources to be patented while the CBD assigns sovereignty to the countries with respect to the biological resources they possess. It is therefore argued that TRIPS takes away rights that are granted by the CBD (The Commission on Intellectual and Industrial Property 1999). Thus, patenting of genetic resources encourages unsustainable use and as a result, promotes biopiracy. Following this, the Doha Ministerial Declaration in 2001 had tasked the TRIPS Council of the WTO to examine the relationship between the TRIPS Agreement and CBD, and the protection of traditional knowledge. Despite a considerable debate on the subject, a common understanding is yet to be reached at the WTO (Ministry of Commerce and Industry 2006).

As a member of the WTO and a signatory to the TRIPS agreement, India is obligated to align its laws on intellectual property rights with the TRIPS agreement. The challenge not only lies in creating these laws, but also in their implementation. The issue becomes worse since a bulk of patent applications in India are filed by foreign companies. As per the data provided by the Indian IP office in its annual report (2017-2018), the applications filed by foreign applicants were more than double (32,304) with respect to those by Indian applicants (15,550). Additionally, there are some inherent conflicts between relevant acts discussed earlier, like NBD and PPVFR. The PPVFR allows free access to traditional knowledge without 'prior informed consent'. This is in conflict with the rules outlined under NBD, wherein, prior approval from NBA is mandatory to access Indian plant genetic resources (Bijoy 2007).

There is, thus, a need to provide appropriate legal and institutional measures for acknowledging the rights of tribal communities on their traditional knowledge resources at the international level. There is also a requirement to introduce mechanisms that facilitate benefit-sharing arising out of the commercial exploitation of traditional knowledge and biological resources. This can be done by harmonising the differences between the CBD and the TRIPS agreement (Ministry of Commerce and Industry: 2006).

In this context, India's position is that patent applicants should be required to disclose the source of origin of the biological resources. India has also advocated that it should be mandatory to obtain prior informed consent (PIC) of the country of origin in the application for an invention under the TRIPS agreement. If these criteria are fulfilled, it would enable domestic legal infrastructure to ensure benefit-sharing with the indigenous communities whose traditional knowledge has been used. To prevent biopiracy, acceptance of the practice of disclosure and PIC by all patent offices across the world is needed.

CONCLUSION

Traditional Knowledge has to be given effective protection, especially in a biodiversity-rich country like India which also happens to be a developing country. Such protection should be both in the form of recognition of rights of the original indigenous knowledge holders, as well as against the unauthorised acquisition of traditional knowledge by a third party. Most importantly, such protection should be affordable, understandable and accessible to traditional knowledge holders.

In this regard, the Government of India has rolled out the National Intellectual Property Rights Policy in 2016 and established a Cell for Intellectual Property Rights Promotion and Management (CIPAM) to work towards accomplishing IP policy objectives. It has also undertaken a digitisation exercise, recruiting a large number of examiners to increase the patent-grants exponentially. Facilitators have been appointed to encourage start-ups in seeking protection of their IP and to file patent applications. Another important step has been to create a repository of traditional knowledge in the form of TKDL, but at an international level, the need of a legal instrument becomes increasingly urgent in the age of globalisation (Ministry of Commerce and Industry: 2006).

Finally, there is still an urgent need for a *sui generis*² law as a probable solution for proper protection of traditional knowledge because vague provisions supporting traditional knowledge in the existing laws will not be sufficient.

² A unique law or legal protection.

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