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Protection of Traditional Knowledge in India

FITM
Forum on Indian Traditional Medicine

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List of Abbreviations

ABS	:	Access and Benefit-Sharing
AYUSH	:	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
BD	:	Biological Diversity Act
BDA	:	Biological Diversity Rules
BMCs	:	Biodiversity Management Committees
BR	:	Biological Resource
CBD	:	Convention on Biological Diversity
CGPDTM	:	Controller General of Patents, Designs & Trade Marks
CGRFA	:	Genetic Resources for Food and Agriculture
CSOs	:	Civil Society Organisations
FAO	:	Food and Agriculture Organisation
FITM	:	Forum on Indian Traditional Medicine
FRA	:	The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act
GI	:	Geographical Indication
GR	:	Genetic Resources
IGC	:	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
ILO	:	International Labour Organisation
IP	:	Intellectual Property
IPR	:	Intellectual Property Rights
ISM	:	Indian System of Medicines
ITPGRFA	:	The International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	:	Mutually Agreed Terms
MLS	:	Multilateral System
NBA	:	The National Biological-diversity Act
NBSAPs	:	National Biodiversity Strategies and Action Plans
NGO	:	Non-Governmental Organisation
NIPR	:	National Intellectual Property Rights
PBR	:	People's Biodiversity Register
PIC	:	Prior Informed Consent
PPVFRA	:	The Protection of Plant Varieties and Farmers' Rights Authority
RIS	:	Research and Information System for Developing Countries
SBBs	:	State Biodiversity Boards
SRISTI	:	Society for Research and initiatives for Sustainable Technologies and Institutions
TK	:	Traditional Knowledge
TKDL	:	Traditional Knowledge Digital Library
TKRC	:	Traditional Knowledge Resource Classification
TM	:	Traditional Medicine
TMK	:	Traditional Medicinal Knowledge
TRIPS	:	Trade-Related Aspects of Intellectual Property Rights
UNDRIP	:	United Nations Declaration on the Rights of Indigenous Peoples
UNO	:	United Nations Organisation
UPOV	:	International Union for the Protection of New Varieties of Plants
WHA	:	World Health Assembly
WHO	:	World Health Organisation
WIPO	:	World Intellectual Property Organisation
WTO	:	World Trade Organisation

SCOPING PAPER

Protection of Traditional Knowledge in India

This series of Scoping Papers presents a brief outline of the major components of studies that FITM undertakes.

This Scoping Paper maps, with reference to protection of traditional knowledge, international regimes and intergovernmental organisations, legal provisions on protection of traditional knowledge in select countries and legal instruments and civil society/ NGO initiatives in India.

An in-depth study undertaken thereafter will analyse these international and domestic components with the objective of identifying issues that India must address internationally and domestically. This will facilitate in designing policy frameworks and appropriate responses during international deliberations at platforms such as WIPO IGC.

Introduction: Context, Rationale and Scope

Context

Growing commercial use of Traditional Knowledge (TK) based resources also makes them increasingly vulnerable to misappropriation and misuse by third parties. The interconnectedness of national and global legal regimes on TK protection and constant evolution of the debate calls for policy efforts towards adapting to changing requirements. The National Intellectual Property Right (NIPR) Policy, 2016, acknowledges that there is 'considerable unexplored potential for developing, promoting and utilizing traditional knowledge of India' and the need to reach out to the less visible Intellectual Property (IP) generators like the Traditional Knowledge (TK) holders. The AYUSH Policy 2002, and the draft AYUSH Policy 2016, too support promotion of the Traditional Medicine (TM) industry. Additionally, the National Health Policy 2017 seeks mainstreaming of AYUSH systems at par with the modern medicines. These policies imply a move towards greater utilisation of TK, in particular traditional medicinal knowledge, which, in turn, leads to concerns on protection of the associated resources.

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As one of the 17 mega diverse countries in the world (with over 47,000 species of plants),[1] Indian Systems of Medicine (ISM) and traditional health practitioners have had knowledge of medicinal usage of more than 7000 plants species.[2] More than 90 per cent formulations of Ayurveda, Siddha and Unani systems of medicine are plant based. Equally rich is the TK on agriculture where farming communities have identified valuable genes and traits in crops and maintained them over generations.[3] In the past, several cases of IP misappropriation of Indian TK have been documented. Examples include patents granted on wound healing properties of turmeric[4] and fungicidal properties of *neem*.[5] More recently, efforts to claim copyright over yoga postures[6] and attach a trademark to Yoga[7] have been reported, implying that in the absence of an international regime on TK, this misappropriation may continue. The integration of TK into business models as in the case of Yoga and the use of Intellectual Property Rights (IPRs) and commercialization generate further dilemmas for traditional communities.[8] Challenges to protection of TK exist both domestically and internationally. Despite several Indian legislations related to protection of TK, instances of misappropriation remain.[9] More crucially, many forms of TK remain legally unprotected and vulnerable to misappropriation in foreign jurisdictions. India has therefore been an active participant in TK related international deliberations, advocating an international regime to prevent illegal bio-prospecting and protecting rights of knowledge holders.

International legal instruments for TK protection has been discussed in various global fora. These include the Convention on Biological Diversity (CBD) and the World Intellectual Property Organisation (WIPO), a specialized agency of the United Nations Organisation (UNO). Established in 2000, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) at WIPO is a "forum where WIPO member states discuss the intellectual property issues that arise in the context of access to genetic resources and benefit-sharing as well as the protection of traditional knowledge and traditional cultural expressions."[10] At the WIPO IGC, a divide exists between *demandeur* countries (including India) seeking protection for TK, rights to knowledge holders, and patent disclosure requirements and *non-demandeur* countries that view these provisions as hindering innovation.

In this background an in-depth study on Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources is being taken up under the aegis of the Forum on Indian Traditional Medicine (FITM). The negotiating position that India takes is based on the twin objectives of effectively promoting innovations based on TK while ensuring benefit sharing for knowledge holders and preventing misappropriation of such knowledge for commercial exploitation. The study intends to provide policy makers with clarity on related issues to facilitate informed responses at global deliberations on TK such as the WIPO and appropriate actionable inputs for domestic policy interventions.

Rationale for present study: literature survey

An expansive literature has studied protection of TK. These broadly highlight challenges to protection related initiatives on TK. For example WIPO's *Report on Fact Finding Missions* (2001), and WIPO's *Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge* (2004) provide brief information about the patent protection for TK available in different jurisdictions. Some studies have examined the proposals before the IGC and have taken note of the discussions therein. David Vivas-Eugui (2012) examines the various issues raised in the IGC's deliberations, implications of the legal texts at the Committee and makes recommendations regarding processes, substantive contents and identification of existing research gaps. The study, however, is more in the context of genetic resources and the Nagoya Protocol. *Protection of Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (2017) is one of the latest studies on deliberations on TK at the WIPO. This volume presents the first comprehensive overview of the IGC's work and includes contributions from scholars, policymakers,

industry representatives, civil society groups and indigenous people's representatives. It provides a brief overview on India's position at the IGC. Besides, several reports on WIPO deliberations on the protection of TK are in the public domain. A sizable literature on protection of traditional knowledge of biodiversity, agriculture, medicines and cultural expressions in India also exist. These include several studies by RIS such as Fakim, A.G. and Srinivas. K. Ravi. (eds) (2015) on potential for cooperation on traditional medicines in the Indian Ocean region, Chaturvedi, *et al.* (eds) (2014) on traditional medicine policies in China and India, Dhar, *et al.* (2014) on access and benefit sharing under the Biological Diversity Act 2002, Chaturvedi, S. (2007) on IPRs and access and benefit sharing, Ragavan, S. and Mayer. J. (2007) on community rights and IPR Regime, Dhar, *et al.* (2001) on IPR regimes on protection of biodiversity and Chaturvedi., S. and Chauhan. K.P.S (2001). Other RIS publications include book on traditional medicine in BRICS (2016), Report on trade, biodiversity and multilateral environmental agreements (2006) and Policy Briefs such as James *et al.* (2017) on Traditional Knowledge Digital Library (TKDL) and James and Pathak (2018) on Traditional Chinese Medicine.

A holistic study on TK protection in India with reference to all major legal, regulatory and civil society initiatives is yet to be made. With reference to India's policy responses at WIPO for protection of TK, a detailed analytical assessment of the past responses and strategy suggestions for future participations has also not yet been made. In addition, available literature has not made a comprehensive study of India's efforts to protect TK with reference all existing related international regimes.

Scope

The purpose of this scoping paper is to provide a brief overview of the national and international instruments related to protection of TK. This mapping of Indian legislations, regulations, institutions, international regimes and organisations and select countries' efforts towards protection of TK is intended to provide a foundation for an in-depth study on TK protection that is to follow thereafter. It examines, among other international instruments, the WIPO IGC documents where India is closely engaged in discussions on IPRs related to TK protection.

1. Indian Policy Regulations, Institutions, Initiatives

1.1 Biodiversity access provisions

India has a rich resource of medicinal plants and traditional crop varieties and TK associated with these resources. Indigenous and local knowledge on conservation, sustainable use of forests, plant and crop varieties have played an important role in this regard. Forest inhabitants and local communities (including farming communities) often have an intimate knowledge of cultivated plant genetic resources and medicinal value of existing biodiversity resources developed from experience gained over centuries, adapted to local environment and transmitted through generations. Legislations regulating access to biodiversity, plant genetic resources and forest related legislations, therefore, form an important component of TK protection in India.

The Forest Conservation Act, 1980

The provisions of the Forest Conservation Act restrict and regulate the de-reservation of forests or use of forest land for non-forest purposes without the prior approval of Central Government. The Act lays down the pre-requisites for the diversion of forest land for non-forest purposes.[11] The legislation may be seen as being aimed, *inter alia,* at conservation and protection of medicinal plants. The Act was amended in 1988 and revised and comprehensive rules and guidelines were issued in 1992.

The Protection of Plant Varieties and Farmers' Rights Act, 2001

The Protection of Plant Varieties and Farmers' Rights Act, 2001, (PPVFRA) was enacted to fulfil India's obligations under Article 27 (3)(b) of the TRIPS Agreement. It recognizes the role of farmers as cultivators and conservers, and the contribution of traditional, rural and tribal communities in the

country's agro-biodiversity by making provisions for benefit sharing and compensation and also protecting the traditional rights of the farmers, including protection for the rights of the producers of new varieties of plants in the traditional way of breeding.[12] Among other provisions for recognition of TK of farmers, it stipulates benefit sharing,[13] recognition and reward (through the Gene Fund) for farmers engaged in the 'conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation'.

Protection of Plant Varieties and farmers Rights' Authority: The Protection of Plant Varieties and Farmers' Rights Authority (PPVFRA) is also an agency concerned with protection of TK. The main functions of the Authority with relevance to protection of TK are:

- Documentation, indexing and cataloguing of farmers' varieties.
- Registration of extant varieties.
- Maintenance of the National Register of Plant Varieties and
- Maintenance of the National Gene Bank.[14]
- Recognizing and rewarding farmers, community of farmers, particularly tribal and rural community engaged in conservation, improvement, preservation of plant genetic resources of economic plants and their wild relatives.[15]

The Biological Diversity Act, 2002[16]

The Biological Diversity Act (BDA), 2002 was enacted to fulfil India's obligations towards CBD and is one of the important legislations on protection of TK. The BDA, along with the Biological Diversity Rules, 2004 (BDR) and the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, provides the main access related legislation in India. It does not refer to TK *per se*; the provisions refer to TK as one 'associated with ....biological resource (BR) which is derived from India'.[17] The provisions which are applicable to ownership of BR are also applicable to TK.

Access Provisions: The BDA delineates the conditions under which persons, commercial firms, and other institutions can access biological resources occurring in India and the knowledge associated with the BR, for research or for commercial utilisation or for bio survey and bio utilisation[18]. Given India's federal structure, the BDA establishes a three-tier system for regulating access to biological resources, at national, state and local levels. The AYUSH industry, particularly MSME sector, and researchers have many concerns about the access provisions of the Act.

Benefit Sharing: The BDA also contains elaborate provisions for benefit sharing arising out of utilisation of the biological resources.[19] The National Biodiversity Authority (NBA) is vested with regulating activities and issuing guidelines for benefit sharing[20]. Benefit claimers are defined as "conservers of biological resources, their by-products, creators and holders of knowledge relating to the use of such biological resources, innovations and practices associated with such use and application"[21]. The BDA with BDR and Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014, provides for both monetary and non-monetary benefit sharing along with national, state and local biodiversity funds[22] for channelizing benefits for local communities conserving the knowledge of the resources.

National Biodiversity Authority (NBA): The NBA formed under the mandate of the BDA is the main body for granting approval for access to biological resources, for applying for IPRs on any invention based on any research or information on a BR obtained from India and for transferring the results of any such research[23]. It can oppose IPRs in India and any country on claims based on BR obtained in India. It ensures equitable benefit sharing of biological resources accessed in India and advises Central and state governments on matters of biodiversity conservation and benefit sharing. The BDA enables the NBA to provide for fair and equitable benefit sharing on the access to biological resources and associated TK. As of 31st August 2018, the NBA has granted 838 approvals for access, transfer of research, filing of IPRs, etc.[24]

State Biodiversity Boards (SBB): State Biodiversity Boards (SBBs), set up as per BDA, regulate commercial

utilization, bio-survey and bio-utilization of biological resources and associated TK by Indian citizens.[25]

Biodiversity Management Committees: The BDA provides for constitution of Biodiversity Management Committees (BMCs) by local bodies for promotion and documentation of, among others, knowledge related to biodiversity in the form of PBRs[26] in consultation with the local people.[27] The purpose of the BMCs is aimed at giving local communities rights in decision making on access to resources in their territorial jurisdiction. As of 31 March 2018, there are 74,063 BMCs. With the exception of Jammu and Kashmir, Haryana and Bihar, BMCs have been formed in all states.[28]

Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006[29]

The Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 (FRA) may be seen as a legislation aimed at vesting forest rights and occupation of forest land in forest dwelling Scheduled Tribes and other traditional forest dwellers, who have been residing in such forests for generations. It recognizes the right of access to biodiversity and community right to intellectual property and traditional knowledge related to biodiversity.[30] It also statutorily empowers holders of forest rights and their *Gram Sabhas* (Village Assemblies) to protect wildlife, forests and biodiversity as well as their habitats. FRA is the first legislation in India that involves the village assembly in the exercise of delineation of forest rights.[31]

1.2 IPR Provisions

From the perspective of potential impact on traditional knowledge protection, the forms of IP that are important are patents, copyrights, trademarks, plant variety protection and Geographical Indications (GIs). The Office of the Controller General of Patents, Designs & Trade Marks[32] (CGPDTM) administers the Patents Act, 1970, the Designs Act, 2000, the Trade Marks Act, 1999 and the Geographical Indications of Goods (Registration and Protection) Act, 1999. It directs and supervises the functioning of: i. The Patent Office (including the Designs Wing) ii. The Patent Information System, iii. The Trade Mark Registry and iv. The Geographical Indications Registry. In 2017, the CGPDTM has issued 'Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material' to help patent examiners analyze what constitutes novelty and inventive step in TK related invention.

The Patents Act, 1970.[33] The Patents Act has a provision wherein "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components"[34] is not an invention and, hence, not patentable. The Act defines an invention as a new product or process involving an inventive step and capable of industrial application".[35] Further, "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances"[36] is not an invention and, hence, not patentable. Additionally, sections 3 (b), (c), (d), (f), (h), (i) and (j) are of relevance with respect to the patent applications related to TK and/or biological material. Traditional knowledge of breeding methods is protected from being patented by a provision that excludes "essentially biological processes for production or propagation of plants and animals".[37] Moreover, applications for patents based on TK, "oral or otherwise, available within any local or indigenous community in India or elsewhere" and/or biological material contravening the provisions of law can be refused[38] in pre-grant opposition[39] and granted patents can be revoked in post-grant opposition.[40,41] This provision enables protection of traditional medicinal knowledge (TMK) anywhere in the world from being granted patents. As per the Patents Rules, 2003, a patent applicant has to disclose the source of the biological resource used in the invention and permission of the competent authority to access the same and, therefore, by extension, of the associated traditional knowledge, if any. Nondisclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification also forms a ground for pre-and post-grant opposition as well as revocation of the patent.[42]

Patents and the BDA 2002: If a person applies for a patent for an invention based on biological resources and/or associated TK, permission of the NBA is required to be furnished, though this can be done even after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.[43] This implies that the NBA has a decisive role on matters related to IPRs over TK associated with biological resources. This has major implications for innovations in Indian Systems of Medicine (ISMs) as such innovations generally require access to biological resources. There have been instances of patented innovations in India based on TK and one celebrated case is that of Jeevani, a drug developed by the scientists of Tropical Botanical Garden and Research Institute, Thiruvananthapuram based on the traditional knowledge of the Kani community.[44]

The Geographical Indications of Goods (Registration and Protection) Act 1999:[45] Geographical Indications (GIs) are signs that identify goods originating in a specific locality, region or territory, and enjoy certain quality, reputation or characteristic adducible to the geographical origin.[46] Under the Geographical Indications of Goods (Registration and Protection) Act, 1999, the scope of 'geographical indication' includes such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristic of such goods is essentially attributable to its geographical origin.[47] Names that do not denote the name of a country or region or locality can still be considered for registration as long as they relate to a specific geographical area and are used in relation to goods originating from that region. This provides the leeway for extending protection to famous symbols such as 'Alphonso' mangoes and 'Basmati' Rice. The Act facilitates protection of collective rights of the rural and indigenous communities and their TK. By registering an item which is the product of TK as GI, it can be continued to be protected indefinitely by renewing the registration when it expires after a period of ten years.[48] Under the Act, a GI cannot be assigned or transmitted[49] thus ensuring that it does not pass on to the hands of those who are not holders of the knowledge. The Act also prohibits registration of a GI as a trade mark,[50] thereby preventing appropriation of TK in public domain by an individual as a trade mark. The Act has established a registry [51] known as the GI registry, to facilitate registration of GIs in India. GIs in India have been registered for products ranging from tea and coffee under agricultural category to textiles and carpets under handicrafts category. So far, 323 products have been registered.[52] These include products which are used in ISMs or traditional medicine practices such as *Navara* rice (GI No. 40), and Kamalapur Red Banana (GI No. 115). Some of the registered orange varieties like Coorg Orange (GI No. 27)[53] also claim to have medicinal uses. While the knowledge involved may not get protected under the GI Act, the name receives protection which greatly facilitates access to genuine products by the medical practitioners. In cases of such products the name and the product are closely related and the TK is with reference to the particular product. The use of GIs to secure protection for ISM products and knowledge base may have to be explored further.

The Trade Marks Act, 1999: Trademarks are indications of distinctiveness that a trade mark holder may affix on a product for which that mark is registered. Like other trademark legislations, the Indian Act does not protect the knowledge or technology incorporated in a trademarked product and, hence, does not impede the commercialization by a third party of an imitative product, if not protected under the Patents Act, under a different trade mark, or without a trade mark. Two particular categories of trademarks are, however, employed to identify the goods' geographic origin and assist in the protection of TK associated. This includes Certification and Collective marks. Certification marks indicate that the product meets pre-established standards, which can be linked to its place of origin. Collective marks distinguish the goods or services as having a connection with a specific group and can also imply a geographic origin. Trademarks can be used to secure protection for the ISM practices since GI Act does not cover services whereas Trade Marks Act

extends to services as well. *Jeevani* referred to above was also registered as trademark.[54]

1.3 Registers and libraries

Traditional Knowledge Digital Library: India undertook defensive protection of TK through the development of a digital database in the form of the Traditional Knowledge Digital Library (TKDL) in 2001, the earliest and most comprehensive database globally.[55] It is arranged in a patent search friendly format, is accessible in five international languages and is based on an innovative classification system Traditional Knowledge Resource Classification (TKRC). It serves as an important source of information on prior art on the Indian systems of medicine. Internationally, the TKDL is accessible to 12 patent offices[56] but other patent offices can seek access subject to the conditions laid down by the TKDL authority. Till date, in 225 cases the patent applications have either been withdrawn/cancelled/declared dead/terminated or have had claims amended by applicants or rejected by the Examiner(s) on the basis of TKDL submissions.[57] The TKDL is considered a pioneer initiative to prevent misappropriation of the country's traditional medicinal knowledge.

People's Biodiversity Registers: The Biological Diversity Rules, 2004 stipulate that "the main function of the BMC is to prepare People's Biodiversity Register (PBR) in consultation with local people. The Register shall 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.[58]" So far 6,096 PBRs have been formed.[59] The existence of expansive data with PBRs necessitates safeguards to ensure protection against misappropriation.

1.4 National policies

National Biodiversity Action Plan:[60] There are two mandatory unqualified obligations of CBD on all Parties, i.e., preparation of National Biodiversity Strategies and Action Plans (NBSAPs)[61] and National Reports.[62] India has updated its second generation NBSAP 2008 by developing 12 National Biodiversity Targets (NBTs) in consultation with stakeholders, which are included in Addendum 2014 to NBSAP 2008.[63] The Action Plan has very specific provisions for protection of TK such as developing *sui generis* system for protection of TK and related rights including IPRs (Point 48), documenting bio-resources and associated knowledge (Point 120), promoting and strengthening TK and practices (Point 130), and harmonising provisions concerning disclosure of source of biological material and associated knowledge used in the inventions under the Patents Act, PPVFRA, and BDA, to ensure sharing of benefits by the communities holding TK, from such use (Point 138).

National Forestry Policy (2016 draft): National Forestry Policy (2016 draft)[64] provides that special communities at the *Gram Sabha* level be created to take over management of forests. The plans prepared by the *Gram Sabhas* for their forestlands would also have to be vetted by the forest department based on the rules prepared for the same, such as wider management plans that the forest department prepares.[65] The draft Policy provides for the involvement of TK holders in the management of certain aspects of forest management (Point 4.7.6).

National Wildlife Action Plan 2017-2031: The National Wildlife Action Plan (2017-2031) is the third, the first two having been implemented from 1983 to 2001 and from 2002 to 2016. Some of the key features of the Plan are conservation of threatened species of flora especially local endemics and highly traded species such as medicinal plants and orchids, identification and validation of TK available in various parts of the country and use of mobile technology to develop 'Digital Field Guides' for easy identification of various wildlife goods and their derivatives.[66]

National Environment Policy, 2006 : Among others, the National Environment Policy, 2006 calls for enhancing and conserving environmental resources which includes biodiversity and traditional knowledge (Section 5.2),[67] and utilize TK for environment conservation and 'unlocking the value of genetic diversity', encourage cultivation of traditional varieties of crops and traditional water conservation efforts,

among others. It calls for harmonizing the Patents Act, 1970 with the Biological Diversity Act, 2002.

National AYUSH Policy 2002[68]*:* Recognizing that ISMs have not been accorded due importance in healthcare, the National AYUSH Policy of 2002 sought to provide policy support to research, financing, education, drug standards regulation and enforcement of traditional medicine systems.

National Health Policy 2017 The National Health Policy's (2017) protection of TK has to be viewed through its provisions for promotion of TM in the healthcare sector, at the educational level, promotion of market linkages of medicinal plants and community healers practicing local health traditions. It seeks 'integration of AYUSH systems at the level of knowledge systems', 'recognizes the need for integrated courses for Indian System of Medicine, Modern Science and Ayurgenomics' and seeks to 'further the development of sustainable livelihood systems through involving local communities and establishing forward and backward market linkages in processing of medicinal plants' and 'strengthen steps for farming of herbal plants'. In addition it recognises the need for 'developing mechanisms for certification of 'prior knowledge' of traditional community health care providers and engaging them in the conservation and generation of the raw materials required, as well as creating opportunities for enhancing their skills'.[69]

1.5 Civil society

Non-Governmental Organisations (NGOs) and Civil Society Organisations (CSOs) have played an important role in protecting TK, with conservation of genetic resources being undertaken by institutions like M.S. Swaminathan Research Foundation, Gene Campaign and Navdanya. Research, documentation, promotion and advocacy on TK protection has been undertaken by Kalpavriksh, the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), Deccan Development Society, CUTS international, ATREE and Centre for Indian Knowledge Systems. The role of grassroots organisations and civil society has been critical in the development of the narrative on TK protection and also in legislations related to TK protection such as Biological Diversity Act and Protection of Plant Varieties and Farmers' Rights Act.

2. International Regimes and Organizations on TK

Traditional knowledge is being addressed in various international fora and agreements. From an environmental and conservationist perspective, it is addressed by the CBD and its Working Group on Article 8(j) and other relevant provisions, and the voluntary Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization;[70] and Food and Agricultural Organisation's (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture.[71] From IPR and trade perspectives, it is addressed by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO; and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the TRIPS Council of the World Trade Organization (WTO). In general, there are distinct national (and in certain cases regional) laws that establish and regulate IP rights and these govern access to genetic resources associated with TK. These national frameworks correspond to international legal frameworks that exist with reference to TK. These treaties fall under two categories: one, relating to conservation and another related to IPRs.

2.1 World Trade Organisation (WTO)

The most comprehensive international treaty on IPRs is the TRIPS Agreement of the WTO. The Agreement does not provide protection to TK as such, though provisions which can be interpreted as indirectly relating to protection of TK may be categorized under patents, copyrights, trademarks, GIs and plant variety protection.

Patents: TRIPS requires that patents may be granted to only inventions that are new, involve an inventive step and are capable of industrial application.[72] WTO Members may define the respective criteria of novelty, inventive step and industrial

application in light of their policy priorities and needs, but the patent period must be not less than 20 years. Compared to scientific knowledge, the nature of TK, including non-documentation in many cases, makes it difficult to find the particular state of art in TK. This creates complications in contesting patent claims based on TK and in identifying the innovation and the contributions made by an innovator.

Plant variety protection is not governed directly by the TRIPS Agreement. It allows governments to exclude certain kinds of inventions from patenting, i.e. plants, animals and "essentially" biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). The Agreement only mentions that plant varieties are eligible to receive some form of either *sui generis* or patent protection, or a combination of both.[73] Hence, countries like India have enacted plant varieties legislations towards IPR protection of TK associated with the same.

The TRIPS Agreement provides for a review of Article 27.3(b) where provisions of that subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. The Doha Declaration 2001 paragraph 19 mandates the TRIPS Council to look at the relationship between the TRIPS Agreement and the CBD, the protection of TK and folklore. Developing countries have argued for the need to re-examine the implications of allowing the so-called 'patenting of life', including examining the impact of patenting genes, viruses and other living organisms.[74] So far there has been very little substantive progress at the TRIPS council regarding the issue of relationship of the CBD and TRIPS agreement and on the protection of TK itself.

Disclosure of Origin of the BR used in an invention in the patent application is also one of the proposals put forth by developing nations in the WTO. This includes introducing requirement on patent applicants to disclose origin/source of GRs and associated TK as amendment to Article 29.[75]

Copyrights: The TRIPS Agreement does not itself define the contours of copyright and instead incorporates the substantive provisions of the Berne Convention text of 1971, including the term of protection as the life of the creator plus 50 years. Article 9 of the TRIPS Agreement does stipulate, however, that copyright protection extends to expressions and not ideas, procedures, methods of operation or mathematical concepts as such. Original narrations of TK including TMK will come under the scope of copyright.

GIs and Trademarks: The current text of TRIPS provides two different standards of protection for GIs, one a basic standard of protection for all products,[76] and a higher standard specifically for wines and spirits.[77] TRIPS also require negotiations to be undertaken in the TRIPS Council concerning the establishment of a multilateral register of geographical indications for wines. The level of protection for TK under GI laws has already been explained above.

2.2 World Intellectual Property Organization

The World Intellectual Property Organisation (WIPO) has been for more than two decades facilitating a normative process among its members aimed at developing international instruments for protection of TK and technical assistance in complementary capacity building to the Member States. It has a separate Division for Traditional Knowledge and has developed a toolkit providing practical guidance on TK documentation. It also maintains a non-exhaustive list of online databases and registries of TK and GR maintained and managed by countries and organisations. In 2007, its General Assembly adopted a set of 45 recommendations under the WIPO Development Agenda which also stressed the importance of developing legal instruments for protection of TK (No. 18).[78]

The Patent Cooperation Treaty (PCT), 1970 administered by the World Intellectual Property Organisation has 152 Members; Under the PCT there are 22 Preliminary Searching Authorities and International Preliminary Examining Authorities. Indian Patent Office is one such Authority. The PCT follows the International Patent Classification System, which now includes Traditional Knowledge resources under separate classifications. In addition, two

journals on TK have been included in the Minimum Documentation under the PCT.[79] These measures contribute to defensive protection for TK.

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) established under the WIPO in 2000,[80] provides a forum for negotiations on issues underlying development of a binding international instrument on TK. Negotiations at the WIPO IGC on IP and TK, traditional cultural expressions (TCEs)/ folklore and Genetic Resources (GRs) have resulted in draft articles providing for three international instruments for the protection of TK, TCE, and the IP issues related to GR (IP/GR) respectively. The draft texts on these respective topics are heavily bracketed,[81] indicating that the IGC Members are as yet not in agreement on a number of issues. Major issues in the negotiations concerning the text on TK include the question of what constitutes public domain, the subject matter of protection, the beneficiaries of protection, and exceptions and limitations.[82] The negotiations continue to have the clear divide between the industrialised countries and the developing countries, the former do not agree to mandatory legal obligations and the latter continuing to insist on the same. The continuing discussions warrant in-depth analysis for adopting negotiation positions.

India has been consistently stressing the importance of protection of TK and associated resources, based on its own domestic legislations. With like-minded parties from Africa, Asia and South America, India has been arguing for a *sui generis* system of protection based on one or more international agreement(s) on the same. India has also expressed that traditional knowledge databases can only ensure defensive protection and not positive protection which is needed in view of the dynamic nature of the TK. The traditional ways of creativity and innovation deserve to be protected like modern scientific innovativeness. It also argued for extension of collective rights to the holders of such knowledge in the way collective ownership is available to producers of goods bearing geographical indications. "As regards eligibility of protection, India's view was that codified and regulated TK like the traditional systems of healthcare, such as Ayurveda, Siddha and Unani, should be included to be accorded protection as a priority, through legal or other measures."[83]

2.3 Food and Agriculture Organisation (FAO)

The first extension of the concept of TK came with the emergence of the concept of farmers' rights in FAO.[84] They were further defined in FAO Resolution 5/89 as "Rights arising from the past, present and future contribution of farmers in conserving, improving and making available Plant Genetic Resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for 'present and future generations of farmers, for the purpose of ensuring full benefits of farmers and supporting the continuation of their contributions…''.

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) 2001:[85] Negotiated under the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) passed in 2001,[86] provides for protection relating to 'farmers rights' including TK and traditional breeding practices.[87] It identifies three measures to protect and promote farmers' rights: a) Protection of traditional knowledge relevant to PGRFA, b) The right to equitably participate in sharing benefits from the use of PGRFA, and c) The right to participate in national decision-making on conservation and sustainable use of PGRFA.[88] It states that "nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed."[89] The ITPGRFA also creates a multilateral system (MLS) for ABS.[90] In the context of Access and Benefit Sharing (ABS) and TK, it is important to note that the farmers' rights as codified in the ITPGRFA deal with benefit sharing but not with access aspects.

2.4 International Union for the Protection of New Varieties of Plants (UPOV) 1961

The International Union for the Protection of New Varieties of Plants (UPOV) was created by the International Convention for the Protection of New Varieties of Plants (entered into Force in 1968 and

amended in 1991) and provides rights and *sui generis* IP protection for new varieties of plants developed by breeders. India is not yet a member of UPOV. The UPOV Convention does not contain any provisions for recognizing the knowledge and contributions that indigenous and local make towards plant breeding programs although, subject to exceptions, grant of a plant breeders' right under UPOV provides the right to exclude others from the use of the variety without a licence. Hence, while UPOV outlines plant breeder exceptions for private and non-commercial purposes, for experimental purposes, and for purpose of breeding other varieties,[91] plant breeders' rights can be used to misappropriate GR and related TK. UPOV secretariat also holds that disclosure of origin cannot be accepted as an additional requirement for protection, since the conditions for plant variety protection under the UPOV Convention have already been established and cannot be increased.[92] Biodiversity rich countries such as India and Thailand have opted to establish a *sui generis* system of plant variety protection outside of the UPOV framework. Pursuant to an agreement concluded between the WIPO and UPOV, the Director General of WIPO is the Secretary-General of UPOV and WIPO provides administrative and financial services to UPOV.[93]

2.5 The Convention on Biological Diversity, 1992

The Convention on Biological Diversity (CBD), along with the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), establishes the leading international regime for protection of TK and recognition of rights of knowledge holders. Under Article 8(j) of the CBD, Parties are required to respect and maintain knowledge held by indigenous communities, and to encourage wider application of TK based on fair and equitable benefit-sharing.[94] TK is recognised as a crucial 'technology' for effective practices of conservation and sustainable use of biodiversity[95] with procedural requirements established[96] for access to genetic resources including access to be based on prior informed consent (PIC) and mutually agreed terms (MAT). Intellectual Property in CBD is only referred to in the context of technology transfer.[97] IPR may be an issue affecting access and transfer of technology and thus play a part in structuring the frame of mutually agreed terms. The Nagoya Protocol which entered into force in 2014,[98] establishes a regime governing access and benefit-sharing (ABS)[99] specifically those relating to: access to genetic resources and TK based on Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT),[100] mandatory benefit-sharing obligations,[101] recognition of community protocols and customary use of GRs and TK among Indigenous local communities[102] and compliance and monitoring measures.[103] India ratified the Nagoya Protocol in 2012.

2.6 ILO Convention

The International Labour Organisation (ILO) Convention 169, concerning Indigenous and Tribal Peoples in Independent Countries, entered into force in 1991. ILO 169 recognizes the need to respect the special importance of people's relationship with their lands and territories, in particular the collective aspect of this relationship, for their cultural and spiritual values. The Convention provides a key instrument for protecting indigenous peoples' rights as it is legally binding. However, it does not specifically address the protection of TK, and it has only been ratified by 20 countries.[104] The particular importance of this Convention for indigenous peoples living in its Member States specifically in the context of TK and IPRs was recently underlined by a judgement of the Supreme Court of Costa Rica. While supporting the future patentability of inventions "essentially derived from the knowledge associated with traditional biological practices or cultural practices in the public domain" in Costa Rica, the Supreme Court also stated that such an amendment "is a change that directly affects the interests of indigenous communities, and, as a result, in conformity with the ILO 169 Convention this amendment must be consulted…"[105] This judgement supports the call by indigenous peoples' organisations to be formally included in the development of national ABS and IP regulations that would cover their genetic resources and TK.

2.7 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIPS) 2007[106]

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIPS), 2007 is so far the most explicit recognition in a human rights instrument of a specific set of rights over various items that are potentially covered by the ABS regime, including TK and TCEs, as well as the manifestations of their sciences, technologies and cultures. The Declaration was adopted by the UN General Assembly in 2007 and addresses the rights of indigenous peoples on subjects including knowledge, land, territories, and resources.[107] For example, Article 18 holds that indigenous people have the rights to participate in decision making in matters that affect their rights, through autonomous selection of representatives in accordance with their own procedures as well as the right to develop and maintain their own indigenous decision making institutions. Article 24 asserts that indigenous people have the right to their traditional medicines and to maintain their health practices , including the conservation of vital medicinal plants , animals and minerals**.** It also declares in Article 31 the rights of indigenous peoples to maintain , control, protect and develop their, among other things, TK as well as the manifestations of "their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora", etc.

2.8 World Health Organisation

The World Health Organisation's (WHO's) engagement with TK is mainly through the regulation of Traditional Medicine (TM). Beginning with the first related Resolution on TM at the 22nd World Health Assembly (WHA) in 1969, the WHO has moved on to implementing its TM strategy including benchmarks for Practice in Traditional and Chinese Medicine. Traditional medicine related activities that the WHO engages in include:

- Facilitating integration of traditional medicine into the national health care system by assisting Member States to develop their own national policies on traditional medicine.
- Promoting the proper use of traditional medicine by developing and providing international standards, technical guidelines and methodologies.
- Acting as a clearing-house to facilitate information exchange in the field of traditional medicine.[108]
- Building on the work done under the WHO traditional medicine strategy 2002–2005, the updated strategy 2014–2023 devotes more attention to prioritizing health services and systems, including traditional and complementary medicine products, practices and practitioners.[109]

3. National Experiences in Protection of TK in Select Countries

Countries have accorded varying levels of protection TK. Many countries have provisions focussing on indigenous communities. For example, Philippines has the Indigenous Peoples Rights Act, 1997 extending protection to the "community intellectual property rights" of indigenous peoples, including their traditional medicines and health practices and indigenous knowledge systems and practices. For this study a limited number of countries from which lessons may be drawn has been proposed for further examination.

Brazil: Brazil has regulated protection of traditional knowledge through the Law on Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge, No. 13.123 dated May 20, 2015.[110] Among the main features of this law is the 'benefit sharing agreement', which provides for one per cent of the total income from sales of a product derived from Brazilian Biodiversity. The focus is more on facilitation of research, innovation and faster access to GRs and TK. Other relevant legislations include Plant Variety Protection Law, No. 9.456, 28 April 1997[111] and Industrial Property Law, No. 9.279, May 14, 1996.[112]

Chile : Under Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3),[122] Article 3 states that 'the present Law shall guarantee that the protection afforded by industrial property rights regulated herein shall be granted while

safeguarding and respecting biological and genetic heritage, as well as national traditional knowledge. The awarding of industrial property rights that constitute protectable elements, developed on the basis of the material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with the law in force'.[123]

China: The Patent Law of the Peoples Republic of China (as amended upto the decision of December 27, 2008,[113] regarding the Revision of the Patent law of the Peoples Republic of China) and the Regulations on the Protection of Varieties of Chinese Traditional Medicine can be described as the main provisions on protection of TK in China.

Ecuador: The Constitution of Ecuador, 2008, recognises the rights of indigenous communities and peoples to "uphold, protect and develop collective knowledge" including their medicine and traditional medical practices."[114] The Intellectual Property Law provides for the establishment of a *sui generis* system for collective IP rights of local communities. The National Biodiversity Policy and Strategy envisages the registration of ancestral knowledge through *sui generis* protection systems.[115]

Mexico: While Mexico does not have specific patent laws or laws to protect TK , provisions regarding industrial property are established in the Law on Industrial Property (LIP), particularly patents in which the link with the use of genetic or biological resources or materials or products derived therefrom are brought out. For example, on biological or genetic materials, Articles 16, 19 and 47 of the LIP are particularly relevant as these are explicitly related to such genetic materials. In Article 16 of the LIP, exceptions to patentability are provided for, some of which are related to genetic resources, biological materials, or biological resources.[116]

Peru: Law No 27811 of July 2002,[117] introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources, is the relevant legislation on protection of TK in Peru. Peru is also the only country in the world that has a commission against biopiracy i.e. the National Commission against Biopiracy (established pursuant to Law No 28216 , May 1, 2004)).[118] The Peruvian law provides for establishment of traditional knowledge registers to preserve and safeguard TK.

South Africa; National Environmental Management: Biodiversity Act, 2004[119] is the relevant legislation with regard to TK protection in South Africa. Additionally, the Patent Amendment Act 2005 (Act No.20 of 2005)[120] regulates patent disclosure with regard to TK.

Thailand: Plant Varieties Protection Act, B.E. 2542 (1999)[121] is the relevant provision related to protection of TK in Thailand.

4. By Way of Conclusion

The issue protection of TK has been on the international agenda for long, but is yet to arrive at a comprehensive solution. Academic studies and jurisprudential developments that impact protection of TK continue. Regular monitoring of international negotiations is needed to put forward cogent arguments by national negotiators. At present, there is an absence of studies that focus on international negotiations. All these bring out the need for in-depth examination of the TK protection measures domestically and internationally to facilitate India's national efforts as well as at international negotiations, particularly at the WIPO IGC. Some of the issues that will be addressed by the study are:

- The sufficiency or insufficiency of the existing national legislations for protecting TK;
- A comparison of India's domestic protection laws with those of select countries;
- Changes, if any, required in the domestic legislations, and need or otherwise for a new legislation;
- An analysis of the various proposals before the IGC; and
- Positions that India can take in the WIPO IGC, in the light of national interest and the national

positions of other similarly placed countries. In particular this will look into

i. Article-wise analysis with special focus on contentious issues like public domain, the subject matter and beneficiaries of protection and exceptions and limitations

ii. Protection of undisclosed TK

iii. TK and existing IP laws

iv. Patent protection of TK and disclosure of source requirement, and

v. Ownership and Rights of Communities on TK

vi. Institutional frameworks that other countries followed.

In-depth study will also explore the following aspects:

- Strengthening implementation of existing legislations through integrated and co-ordinated mechanisms;
- Case Studies of implementation of Indian legislations relating to biological resources and TK including benefit sharing and problems of MSMEs and researchers;
- Impact of implementation of the legislations on the Indian Traditional Medicine industry;
- Development of data-bases on all TK in the country and the uses of the different TK; and
- Protection of undisclosed information.

The study will address the issues identified in this Scoping Paper in detail along with case studies to provide proper inputs to the Government to facilitate appropriate policy and programme responses for developing and promoting ISMs as well as active and informed participation in international negotiations. Based on the case studies, it will propose implementable action points for the government and the stakeholders.

Endnotes

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18 *Ibid* Chapter II

19 *Ibid* Chapter IV, V, VII, XII

20 *Ibid* Sections 3, 4, 6 BDA

21 Section 2(a), BDA

22 *Ibid* Section 27, 32 and 43 respectively

23 *Ibid* Section 4, 6, 18 Biological Diversity Act ,2002

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[33] The Patents Act 1970

[34] *Ibid* Section 3 (p)

[35] *Ibid* Section 2 (1) (j)

[36] *Ibid* Section 3(e)

[37] *Ibid* Section 3(j)

[38] *Ibid* Section 15

[39] *Ibid* Subsections (d), (f) and (k) of Section 25 (1)

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About FITM

The Forum on Indian Traditional Medicine (FITM), set up by the Ministry of AYUSH at RIS, is a platform aimed at contributing towards creation of pro-active strategies for promotion of Indian systems of medicine.

Among others, it supports studies on the issues pertaining to traditional medicines in India and countries that India could emulate from.

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