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TRADITIONAL KNOWLEDGE – THE CHANGING SCENARIO IN INDIA

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Abstract

India is a party to the CBD, which came into force on 29 December 1993. It has three main objectives, namely the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources. CBD envisages that the benefits accruing from commercial use of TK have to be shared with the people responsible for creating, refining and using this knowledge. Art 8(j) of the CBD provides for respecting, protecting and rewarding the Knowledge, Innovations and Practices (KIP) of local communities. Realizing the need to ensure that the holders of TK, which is not still in the public domain should be able to get the benefits arising from the use of such knowledge, an enabling provision has been made for protecting the TK in the Biodiversity Act, 2002. Indian Patents (Amendment) Act, 2005 also deals indirectly with the protection of TK. The main objective of protection would be to obtain recognition and some compensation for the commercial use of TK outside the community or the society, which generated it, either by excluding the unauthorised use by third parties or by ensuring a right to remuneration (or benefit sharing) for such use.

Keywords : *Biological Diversity, Indigenous Community, Traditional Knowledge*

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I. INTRODUCTION

Traditional Knowledge is the root of every country and it is exclusive to a nation. It may help to find out solutions to various problems. It is the inseparable part of communities and is inherited by their ancestors. As every country is not capable of ensuring such protection themselves, there is a pressing need to take steps at an international level. By inculcation access and benefit-sharing system, sui-generis system for legal protection, legal protection under IP law and public domain, efforts have been made at the international level¹.

To address issues of indigenous people the first agency of the United Nations was the International Labor Organization (ILO). It deals with measures

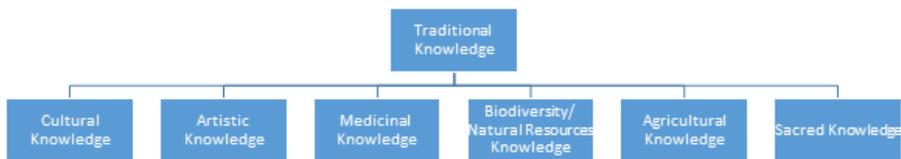
¹ Barnes, J., Anderson, L.A. and Phillipson, J.D., "Evaluation of Toxicological Profile of a Polyherbal Formulation, *Herbal Medicine 3rd Edition, Pharmaceutical Press, London*, (January 2007): 1-23, *References - Scientific Research Publishing*, n.d. Accessed January 10, 2021. [https://www.scirp.org/\(S\(351jmbntvnsjt1aadkpozjce\)\)/reference/ReferencesPapers.aspx?ReferenceID=1656874](https://www.scirp.org/(S(351jmbntvnsjt1aadkpozjce))/reference/ReferencesPapers.aspx?ReferenceID=1656874).

to integrate indigenous people within modern production systems.

As acknowledged in the Doha Ministerial Declaration, the protection of TK is among the important IPR issues to be resolved in the TRIPS Council. Paragraph 19 of the Doha WTO Ministerial Declaration which calls for the TRIPS Council to examine the issue. Traditional Knowledge consists of trade secrets as well as information in the public domain. Countries where the pharmaceutical industry is strongest, novelty thresholds of patent laws differ greatly. WIPO in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has been side-tracked away from substantive issues to procedural ones. Instruments like CBD, TRIPS and the Cartagena Protocol were developed internationally long before countries legislated and created national systems. If one solution cannot suit all countries, a range of policy choices harmonizable with international regimes may need to be envisaged².

With wider objectives, the CBD, through its Art 8(j) has broadened the scope and mandate of protection. There has been lot of effort to protect TK by inter-governmental bodies dealing with IP, environment and even human rights control to the indigenous and local communities over TK, namely, WTO and its Council for TRIPS, FAO, WIPO, UNCTAD and WHO.

Figure 1. Different types of Traditional Knowledge



There is no common agreed definition of Traditional Knowledge. The WIPO defined it as “tradition based literary, artistic or scientific works, performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information and all other tradition based innovations and

² Decaro, Nicola, and Alessio Lorusso, “Novel Human Coronavirus (SARS-CoV-2): A Lesson from Animal Coronaviruses,” *Veterinary Microbiology* 244 (May 2020): 108693, <https://doi.org/10.1016/j.vetmic.2020.108693>.

creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

II. PRIOR ART

The patenting authorities consider the prior art as not qualified for patenting. TK being held and used by indigenous peoples (and researchers as well for their own academic and research purposes) and as there are publications, databases, journals, periodicals and other means through which TK is being disseminated and made public, TK has rarely been recognized and considered as forming part of the state of the art for the purpose of the patent system in general. Patent examiners have undertaken exhaustive searches and review of TK sources. This has caused, especially in the US, problems with patents such as those relating to Neem and Ayahuasca.

Folklore³ is a group-oriented and tradition-based creation of groups or individuals reflecting the expectations of the community as an adequate expression of its cultural and social identity; its standards are transmitted orally, by imitation or by other means. Its forms include, among others, language, literature, music, dance, games, mythology, rituals, customs, handicrafts, architecture and other arts⁴.

III. TRADITIONAL PEOPLE

In the debate about the protection of TK, the implied beneficiaries of this protection are traditional peoples. Invariably, these are referred to as ‘Indigenous Peoples.’ A definitional issue, related to the delineation of the content of TK, is defining the groups or communities who can assert property rights over this knowledge.

A commonly used term is that of the International Labour Convention 169 concerning Indigenous and tribal peoples in Independent Countries, which refers to ‘indigenous peoples’ as “peoples in independent countries whose social, cultural and economic conditions distinguish them from other sections of the national community, and whose status is regulated wholly or partially by

³ Bawa, Kamaljit S., Asmita Sengupta, Vishwas Chavan, et al., “Securing Biodiversity, Securing Our Future: A National Mission on Biodiversity and Human Well-Being for India,” *Biological Conservation* 253 (January 2021): 108867, <https://doi.org/10.1016/j.biocon.2020.108867>.

⁴ El Zowalaty, Mohamed E., and Josef D. Järhult, “From SARS to COVID-19: A Previously Unknown SARS- Related Coronavirus (SARS-CoV-2) of Pandemic Potential Infecting Humans – Call for a One Health Approach.” *One Health* (June 2020): 9, <https://doi.org/10.1016/j.onehlt.2020.100124>.

their own customs or traditions or by special laws or regulations⁵). The Convention on Biological Diversity (CBD) refers to “indigenous and local communities”, thus also including local communities (ie., small farmers), which might not necessary be indigenous, as would a native community in the Amazon or a tribe in India.

The definition of indigenous peoples, which appears to enjoy widest support, is that as “those which, having historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the society now prevailing in those territories or parts of them”. However, it should be acknowledged that a number of representatives of these groups have asserted that the diversity of the world’s indigenous peoples renders problematic an all-embracing definition and that efforts by the international community to develop a binding, all-inclusive definition are a diversion of energies.

‘Indigenous Peoples’ are those peoples who are able to avail themselves of the protections conferred by international instruments such as the UN Charter, which in Article 1 refers to “the principle of equal rights and self determination of peoples.” The International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) also refer to the “right of all peoples to self-determination.” However, the UN General Assembly Resolution 1514(XV) on Granting of Independence to Colonial Countries and Peoples subsequently provided that the rights of peoples are subordinated to the sovereignty of States. This statistic interpretation of the rights of peoples has been a barrier to the recognition of various political and property rights, including intellectual property rights, of indigenous peoples and traditional communities.

IV. NEED FOR PROTECTION

The discourse about the protection of TK assumes the necessity for this protection and also assumes that the primary beneficiaries of this protection will be indigenous peoples and community groups. However, the State as guardian of its people’s cultural heritage also has an interest in the preservation of the TK, which exists within it.

The protection of TK has been advocated in many national, regional and international fora. The provision contained in Article 8 (j) of the Convention

⁵ Garcia, Sònia, “Pandemics and Traditional Plant-Based Remedies. A Historical-Botanical Review in the Era of COVID19,” *Frontiers in Plant Science* (2020):1, <https://doi.org/10.3389/fpls.2020.571042>.

on Biological Diversity (CBD) , as adopted in 1992, triggered a number of proposals to deal with this issue at the national and international level⁶. Most notably, in 2000 an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was established under the auspices of WIPO⁷.

It is recognised that each indigenous community must retain permanent control over all elements of its own heritage. It may share the right to enjoy and use certain elements of its heritage under its own laws and procedures, but always reserves a perpetual right to determine how shared knowledge is used.

The main objective of protection would be to obtain recognition and some compensation for the commercial use of TK outside the community or the society, which generated it, either by excluding the unauthorised use by third parties or by ensuring a right to remuneration (or benefit sharing) for such use. This is most important in the context that more than 80 per cent of medicinal plants are collected from forests or uncultivated sources⁸.

The traditional medical knowledge of indigenous peoples throughout the world has played an important role in identifying biological resources worthy of commercial exploitation. The search for new pharmaceuticals from naturally occurring biological material has been guided by ethno-biological data.

V. TRADITIONAL PROTECTION AT THE INTERNATIONAL LEVEL

Art 12 of the Draft Declaration recognised the right of indigenous peoples⁹. Art 29 recognised the entitlement of indigenous peoples¹⁰. The growth self-realisation of indigenous peoples that the international recognition of

⁶ Muhammad, Faisal. 2020. "COVID-19 Pandemic: The Role of Traditional Medicine," *Letter International Journal of Infection*, (July, 2020), <https://sites.kowsarpub.com/iji/articles/107090.html#abstract>.

⁷ Payyappallimana, Unnikrishnan, Kishor Patwardhan, Prasad Mangalath, et al., "The COVID-19 Pandemic and the Relevance of Ayurveda's Whole Systems Approach to Health and Disease Management." *The Journal of Alternative and Complementary Medicine* (2020): 26, 1089–92. <https://doi.org/10.1089/acm.2020.0370>.

⁸ Prajapati, Suneel, and Narasimha Kumar Gv., "SARS-CoV-2 Pandemic: An Opportunity for Indian Traditional Medicines (AYUSH)." *International Journal of Complementary and Alternative Medicine*, (2020):103–5. <https://doi.org/10.15406/ijcam.2020.13.00502>.

⁹ To practice and revitalize their cultural traditions and customs, including the right..to maintain, protect and develop the past, present and future manifestations of their cultures as well as the right to the restitution of cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs.

¹⁰ To the full ownership, control and protection of their cultural and intellectual property.

their Intellectual Property Rights in their cultural expressions would depend upon their own efforts has resulted in the development of international solidarity through international conferences of indigenous peoples. These conferences have promulgated intellectual property declarations, formulating norms for the protection of TK.

A significant initiative during the UN International Year for the World's Indigenous Peoples was the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, which was convened by the Nine Tribes of Mataatua in the Bay of Plenty Region of Aotearoa, New Zealand in June 1993. The resultant Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous Peoples insisted that the protection of the rights of indigenous people to self determination. The Mataatua Declaration recommended in Art 1 that in the development of policies and practices, indigenous peoples should:

1. Define for the themselves their own intellectual and cultural property.
2. Note that existing protection mechanisms are insufficient for the protection of Intellectual and Cultural Property of Indigenous Peoples.
3. Develop a code of ethics which external users must observe when recording (visual, audio, written) their traditional and customary knowledge.
4. Prioritise the establishment of indigenous education, research and training centres to promote their knowledge of customary environmental and cultural practices.
5. Develop and maintain their traditional practices and sanctions for the protection, preservation and revitalization of their traditional intellectual and cultural properties.

The Mataatua Declaration in Art 2.1 recommended that in the development of policies and practices, States and national and international agencies should recognise that indigenous peoples are the guardians of their customary knowledge and have the right to protect and control dissemination of that knowledge. In Art 2.2 it urged the recognition that "indigenous peoples also have the right to create new knowledge based on cultural traditions." The insufficiency of existing protection mechanisms was asserted in Art 2.3. Art 2.5 provided for the development, in full co-operation with indigenous peoples, of an additional cultural and intellectual property rights regime incorporating the following elements:

1. Collective (as well as individual) ownership; and retrospective cover-

- age of historical as well as contemporary works;
2. Protection against debasement of culturally significant items;
 3. Co-operative rather than competitive framework;
 4. First beneficiaries to be the direct descendants of the traditional guardian of that knowledge;
 5. Multi-generational coverage span;
 6. The conference delegates recommended that the UN incorporate the Mataatua Declaration in its study on Cultural and Intellectual Property of Indigenous Peoples.

Art 9 of the COICA¹¹ statement pointed to the danger of distortion to indigenous systems in adjusting them to the prevailing intellectual property regime. It identified intellectual property principles and mechanisms, which were either inimical to or useful for indigenous peoples. For example, Art 12 recognised that “there are some formulas that could be used to enhance the value of our products, but on the understanding that these are only marketing possibilities, not entailing monopolies of the product or of collective knowledge.

The Statement, in Art 14, proposed the design of a protection and recognition system in the short and medium term of mechanisms, which will prevent appropriation of our resources and knowledge. These would include appropriate mechanisms for maintaining and ensuring rights of indigenous peoples to deny indiscriminate access to the resources of our communities or peoples and making it possible to contest patents or other exclusive rights to what is essentially indigenous.

Although the COICA Statement was largely concerned with indigenous people’s rights in biodiversity, it called for the training of indigenous leaders in aspects of intellectual property.

VI. TRADITIONAL KNOWLEDGE PROTECTION IN INDIA

India is one of the bio-diversity rich countries in the world. But little was done so far for the protection of its vast and rich TK vested in the indigenous communities all over the country. India is one of the twelve mega biodiversity countries of the world. India is also one of the twelve primary centres of origin of cultivated plants and is rich in agricultural biodiversity. India is equally rich

¹¹ Coordinadora de las Organizaciones Indígenas de la Cuenca Amazonica. It is a body of indigenous organizations of the Amazon basin.

in traditional and indigenous knowledge , both coded and informal.

India is a party to the CBD, which came into force on 29 December 1993. It has three main objectives, namely the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources. CBD envisages that the benefits accruing from commercial use of TK have to be shared with the people responsible for creating, refining and using this knowledge. Art 8(j) of the CBD provides for respecting, protecting and rewarding the Knowledge, Innovations and Practices (KIP) of local communities.

Realizing the need to ensure that the holders of TK, which is not still in the public domain should be able to get the benefits arising from the use of such knowledge, an enabling provision has been made for protecting the TK in the Biodiversity Act, 2002. Indian Patents (Amendment) Act, 2005 also deals indirectly with the protection of TK.

VII. TRADITIONAL KNOWLEDGE AND ITS RELATIONSHIP WITH OTHER FORMS OF IP

Patents, copyrights, trademarks, plant variety protection and Geographical Indications are the important forms of IP from the perspective of potential impact on Traditional Knowledge protection. Patents Act, 1970, the Designs Act, 2000, the Trade Marks Act, 1999 and the Geographical Indications of Goods Act, 1999 are administered by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM)¹². To help patent examiners analyse what constitutes novelty and inventive step in TK related invention, in 2017, the CGPDTM has issued ‘Guidelines for Processing of Patent Applications relating to TK and Biological Material’.

A. THE PATENTS ACT, 1970

As per sec 3 (p) of the Patents Act “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components” is not an invention and, hence, not patentable. 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”, as per Sec 3(j) of the Act. Additionally, sec 3(b), (c), (d), (f), (h), (i) and (j) are of rel-

¹² World Health Organization, “Who Global Report On Traditional And Complementary Medicine,” <https://www.who.int/traditionalcomplementaryintegrativemedicine/WhoGlobalReportOnTraditionalAndComplementaryMedicine2019.pdf?ua=1>, accessed January 9th 2021.

evance with respect to the patent applications related to TK and/or biological material. Non disclosure 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 patent¹³.

Under current IP law, there is no obligation for companies, which utilize the traditional medical knowledge of indigenous peoples to provide any compensation to recognise their equality in the commercial application of this knowledge. To be patentable, an invention has to be novel, involving an addition to the existing state of relevant technology. Novelty is assessed by reference to the prior art. Novelty will be destroyed by prior publication.

A problem with the patent claims of indigenous peoples in relation to traditional medical remedies is that it has been the practice of ethno botanists and ethno pharmacologists to publish accounts of the uses of plants by indigenous peoples.

Another obstacle to the recognition of the contribution of indigenous peoples to the development of new drugs, are the fairly strict rules that apply to the concept of joint invention.

Joint inventor ship typically requires that each of the joint inventors must have contributed to the inventive conception, “working toward the same end and producing an invention by their aggregate efforts”. It is not necessary that they worked physically together at the same time and that each made the same type or amount of contribution. However, all must work on the same subject-matter and make some contribution to the inventive thought and to the final result. The economic factor has played an important role in the agitation for the protection of traditional cultural works.

Proposals of mechanisms for the protection of TK have ranged across two axes. Along one axis are various suggestions to improve the private law rights of the creators or custodians of TK. These suggestions range from proposals to modify existing copyright law through to the creation of sui generis TK rights. Along another axis are suggestions to deal with the protection of TK as a public law right. These suggestions range from the creation of a public protection authority, through domaine public payant proposals, to the empowerment of indigenous peoples’ protective agencies.

B. THE PATENT (AMENDMENT) ACT, 2005

¹³ Yuan, Haidan, Qianqian Ma, et al., “The Traditional Medicine and Modern Medicine from Natural Products,” *Molecules*, (2016): 21 (5). <https://doi.org/10.3390/molecules21050559>.

Some important provision introduced by the Patents (Amendment) Act 2005 includes dealing with the post-grant opposition, further stipulates that at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of patent, any person interested may give notice of opposition to the Controller in the prescribed manner on certain specified grounds. Provisions included in the Indian Patents Act in conjunction with the PIC and benefit sharing requirements incorporated in the Biological Diversity Act, 2002 create sufficient room for combating the biopiracy threats at the national level in India¹⁴.

The 2005 amendments to the Patent Act show the recognition of the importance of TK in the country. Legal recognition of TK entails its identification as a separate knowledge system, the recognition that it is intimately weaved into the livelihood and culture of indigenous communities, and understanding its dialectical relationship with the surrounding biodiversity. As far as TK is concerned, the definition of invention is loosely defined. It should be amended properly to exclude patents, which used indigenous knowledge or materials and made an improvement or changes to it.

Sec 2(1) (aba) of the Act mentions about Budapest Treaty for the Deposit of Micro-organisms. It provides that “Budapest Treaty” means the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure done at Budapest on 28th day of April, 1977 as amended and modified from time to time. However, this section does not include the definition of micro-organisms either. Since the *Diamond v. Chakraborty* judgment passed by the US Supreme Court, various commentators have suggested that micro-organisms, though patentable, should be defined in extremely narrow terms. This is because granting monopoly rights like patents on micro-organism always carries with it the risk of restricting accessibility to the resource base, due to the expansionary tendencies of the patent holder claiming ownership rights over all the usage of that resource and consequently the risk of the rights spillover¹⁵. This will adversely affect the resources, which the indigenous community is depending for their livelihood.

It has been suggested that the definition of the term micro-organisms

¹⁴ Zhu, Zhixing, Xihua Lian, et al., “From SARS and MERS to COVID-19: A Brief Summary and Comparison of Severe Acute Respiratory Infections Caused by Three Highly Pathogenic Human Coronaviruses,” *Respiratory Research*, (2020): 21 (1): 224. <https://doi.org/10.1186/s12931-020-01479-w>.

¹⁵ Thorsen, Rikke Stamp, and Mariève Pouliot, “Traditional Medicine for the Rich and Knowledgeable: Challenging Assumptions about Treatment-Seeking Behaviour in Rural and Peri-Urban Nepal,” *Health Policy and Planning*, (2016): 31 (3): 314–24, <https://doi.org/10.1093/heapol/czv060>.

should be arrived at by way of a multi-stakeholder dialogue process. The aim is to limit the exercise of monopoly control over biological resources that are liable to be used by multiple stakeholder groups, including indigenous communities.

Sec 25 and 26 of the Patent Act provide for pre and post grant opposition to the filing of patent. Sec 25 allows third parties to represent to the controller for non-granting of a patent on the grounds of patentability and on non-disclosure or wrongful mentioning in the specification source and the geographical origin of the biological material used in the ‘invention’ and anticipation of it by the knowledge – oral or otherwise – available within any local or indigenous community.

The indigenous community in India may neither have heard of patent nor is knowing the procedure for patenting their indigenous knowledge. It is impossible for them to make opposition to each and every application containing biological or indigenous knowledge. Hence, it should be made mandatory for the National Biodiversity Authority (NBA) to represent the community in cases where the invention claimed was anticipated, having regard to the knowledge available within any local or indigenous community in India where NBA has such information. This will help the indigenous community to prevent bio-piracy of their resources. It is unfortunate that the new amendments do not include any specific provisions for preventing patenting of indigenous knowledge.

C. THE TRADE MARKS ACT, 1999

Collective and Certification marks are two particular categories of trademarks employed to identify the good’s geographic origin and assist in the protection of TK associated. Collective marks distinguish the goods or services as having a connection with a specific group and can also imply a geographic origin¹⁶. Certification marks indicate that the product meets pre-established standards, which can be linked to its place of origin. GI Act does not cover services, whereas Trademarks can be used to secure protection for the ISM practices.

D. THE BIOLOGICAL DIVERSITY ACT, 2002

The BDA, 2002 primarily addresses access to genetic resources and associated knowledge by foreign individuals, companies or institutions, to en-

¹⁶ Oyeboode, Oyinlola, Ngianga-Bakwin Kandala, et al., “Use of Traditional Medicine in Middle-Income Countries: A WHO-SAGE Study,” *Health Policy and Planning*, (2016): 31 (8): 984–91, <https://doi.org/10.1093/heapol/czw022>.

sure equitable sharing of benefits using out of the use of these knowledge and resources to the country and the people. Permission of the NBA is required to be furnished, if a person applies for a patent for an invention based on biological resources and/or associated TK. This implies that the NBA has a decisive role on matters related to IPRs over TK associated with biological resources. In Indian Systems of Medicine (ISMs) as such innovations generally require access to biological resources.

E. THE GEOGRAPHICAL INDICATIONS OF GOODS (REGISTRATION AND PROTECTION) ACT, 1999

GI are signs that identify goods originating in a specific locality, region or territory and enjoy certain reputation or quality or characteristic adducible to the geographical origin. The scope of GI 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 reputation, quality or other characteristic of such goods is essentially attributable to its GI. Under the Act, GI cannot be transmitted or assigned thus ensuring that it does not pass on to the hands of those who are not holders of the knowledge. 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 10 years. For preventing appropriation of TK in public domain by an individual as a Trade Mark, the act prohibits registration of a GI as a Trade Mark. In India, GIs have been registered for products ranging under agricultural category to textiles and carpets under handicrafts category. These include products which are used in ISM products or Traditional Medicine Practices such as Navara Rice, Kamalapur Red Banana, Coorg Orange etc¹⁷. 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 practitioners¹⁸.

F. THE PROTECTION OF PLANT VARIETIES AND FARMERS RIGHTS (PPVFR) ACT, 2001

The Act is a deviation from the 1991 UPOV Model. It deals primarily with the protection of plant breeder's rights over the new varieties developed by them and the entitlement of farmers to register new varieties and also to

¹⁷ Zhang, Ming-Ming, "Effect of Integrated Traditional Chinese and Western Medicine on SARS: A Review of Clinical Evidence," *World Journal of Gastroenterology*, (2004):10 (23): 3500, <https://doi.org/10.3748/wjg.v10.i23.3500>.

¹⁸ Roux-Kemp, Andra le, "A Legal Perspective on African Traditional Medicine in South Africa," *SSRN Scholarly Paper ID 2441501*, Rochester, NY: Social Science Research Network, <https://papers.ssrn.com/abstract=2441501>.

save, use, breed, share, exchange or sell the plant varieties, which the latter have developed, improved and maintained over many generations. It provides a model of an effective sui generis system for protection of plant varieties that WTO members are expected to put in place in fulfilment of their commitment to the Agreement on TRIPS.

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.

G. GEOGRAPHICAL INDICATION AND TRADITIONAL KNOWLEDGE

Food and Agriculture, Human and Animal Health, Clothing, Natural Resources Management, Shelter, Architecture, Culture, Art etc are of the important streams you can find the application of GI and TK. Both GI and TK are location-specific and are emanate or associated from a culture and traditions of a community or a region. Traditional Knowledge is dynamic and evolving. The use of TK related to biological resources is not restricted to the lives and livelihoods of agrarian, rural and indigenous societies. In the modern day, there is an ever-growing demand for herbal, natural and organic products globally, especially in urban markets. The Herbal Medicine, personal care industries and cosmetics are the major users of these resources.

Traditional Knowledge is an inseparable part of the biocultural heritage of indigenous peoples and local communities. Traditional Knowledge, practices and innovations play a key role in practically all aspects of the lives and livelihoods of rural people in India. Products made by local people, using local resources and traditional knowledge may qualify for registration as geographical indications. An official indication of product's origin and goodwill can add or maintain market value in terms of prices that are not available to similar competing products that are not distinguished by their source.

GI affords collective rights and thus is more suited to protection and promotion of TK than most IPR, since TK is largely held collectively. Both GI and TK are location-specific and are emanate or associate from a culture and traditions of a community or a region. There are two kinds of promotion and protection frameworks are required for the losses of TK:-

1. Protection Against Misappropriation and Biopiracy
2. Protection to reverse the decline and loss of TK

GI registration of biocultural products can help conserve biodiversity. It can be used to protect TK indirectly by preventing others from unfairly profiting from a community's TK and by placing value on the TK embedded in goods. Demand for such products can be increased through branding and promotion with unique qualities and thus revitalize traditional production practices and knowledge.

Producers of biocultural products face a range of challenges in the journey to obtain GI registration and the more challenges in the post-registration phase.

VIII. PRE-REGISTRATION CHALLENGES

External Agencies often play a role in promoting, supporting, encouraging and sponsoring the registration of biocultural products. Without the support of external agencies, small producers in developing countries don't typically have the capacity to deal with the complex bureaucratic systems of applying for GI registration and to market the product. Moreover, the process of registration is typically not a short one, requiring financial resources and legal assistance which are beyond the capacity of most small producers.

The costs in the pre-registration phase include expenses related to the registration of a body which will apply for GI registration, mobilization of farmers, engaging a legal expert to develop the case which requires a considerable amount of time to gather archival material to prove that the product emanates from a particular geography. Normally it takes one to two years to get a GI application approved once the application has been submitted and if it is a contested case, the expense increases manifold as one has to make several visits to the Appellate Board.

IX. ISSUES RELATING TO PUBLIC DOMAIN STATUS OF TRADITIONAL KNOWLEDGE AND TRADITIONAL CULTURAL EXPRESSIONS

An increase in emphasis of the need to safeguard 'public domain' is recognised at the international level as more exclusivities are taken particularly in the form of intellectual property rights. There were two parallel international developments that set the discourse of the issue of 'public domain' and 'access'; the Convention on Biological Diversity 1992 and the TRIPS Agreement of 1994. The former has the mandate of common responsibility of countries to conserve and sustainably utilise biological diversity and the latter which

made intellectual property (IP) a tradable good. While the TRIPS agreement brought in IP as a global obligation for its member countries, the Convention on Biological diversity gave impetus to conservation as a global commitment. The scope of public domain considerations gained attention under the fore of WIPO's commitment to reach a mechanism for strengthening a cause for traditional knowledge (TK) and traditional cultural expressions (TCEs). The introduction of the voluntary fund for indigenous community participation and expansion of the work programme under the aegis of the intergovernmental committee on genetic resources and TK are important standpoints in the international developments relevant to TK.

Indigenous peoples, local communities and several developing countries have vociferously argued for the recognition of TK under the IP protection and inclusion of the traditional forms of creativity and innovation. Under the conventional IP system, they are generally regarded as being in the public domain, and therefore free for anyone to use¹⁹. The need to raise traditional knowledge (TK) to the status of one of the Intellectual Properties (IPs) during the TRIPS agreement is justified as it represents intellectual creation of the human mind which has the maximum public good character among the forms of IP. TK has been preserved through generations. It has not only been accepted but also most effectively used and disseminated. TK has a distinct linkage with the identity of a community in relation to culture, tradition, traditional medicine, healing practices, artistic creations, community practices etc,

Indigenous peoples, local communities and many countries reject a “public domain” status of TK and TCEs. These are the inalienable aspects that become open to abuse and misappropriation. For instance, a traditional remedy could be appropriated by a pharmaceutical company and the resulting invention patented by that company, without sharing any of the benefits arising from the commercialization and sale of the pharmaceutical product with the community. In the search for unique compositions, an indigenous folk song could be adapted and copyrighted without the consent of the communities. Benefits that are derived out of such exploitation without any acknowledgement of the indigenous community are rarely shared with the community. The ongoing international developments are centred on according appropriate protection of TK and TCEs. This has led to the need to be identify how, changes should be made to the existing boundary between the public domain and the scope of IP protection²⁰. An integral part of developing an appropriate policy framework

¹⁹ Muhamad Seloom, “The Impact of Covid-19 on International Security,” National Security during the Covid-19 Pandemic, *Arab Center for Research & Policy Studies* (2020), <https://www.jstor.org/stable/resrep25859.7>.

²⁰ Sen, Saikat, and Raja Chakraborty, “Revival, Modernization and Integration of Indian Tra-

for the IP protection of TK and TCEs is a need for clear understanding of the role and boundaries of the public domain.

X. WHAT DOES “PUBLIC DOMAIN” MEAN IN THE IP CONTEXT?

The term “public domain”, in IP law, is generally said to consist of intangible materials that are not subject to exclusive IP rights and which are, therefore, freely available to be used and exploited by any person. It is a versatile, relative and elastic concept that is not susceptible to a uniform legal meaning²¹.

According to Black’s Law Dictionary, the public domain is the universe of inventions and creative works that are not protected by intellectual property rights and are therefore available for anyone to use without charge. When copyright, trademark, patent, or trade-secret rights are lost or expire, the intellectual property they had protected becomes part of the public domain and can be appropriated by anyone without liability for infringement.”

The public domain is considered to be a valuable resource, as it can be argued that innovation that will result in private property, such as a patent or copyright, depends on the existence of a rich public domain²². The need to preserve public domain has been a strong basis for the utilitarian approach and linked to public policy goals. Ensuring longevity of TK and TCEs will help in preserving a vast body of knowledge as well as sustain livelihoods of communities²³.

XI. KEY ELEMENTS OF THE PUBLIC DOMAIN

The public domain encompasses three important elements, or perspectives.

ditional Herbal Medicine in Clinical Practice: Importance, Challenges and Future,” *Journal of Traditional and Complementary Medicine*, (2016): 234–44, <https://doi.org/10.1016/j.jtcme.2016.05.006>.

²¹ Silva, Priscilla Gomes da, João Rodrigo Mesquita, et al., “Viral, Host and Environmental Factors That Favor Anthropozoonotic Spillover of Coronaviruses: An Opinionated Review, Focusing on SARS-CoV, MERS-CoV and SARS-CoV-2.” *Science of The Total Environment*, (January 2021): 750, 141483. <https://doi.org/10.1016/j.scitotenv.2020.141483>.

²² Kasturi Das, “Protection of Geographical Indications: An Overview of Select Issues with Particular Reference to India,” *SSRN Electronic Journal* (February 2007), <https://doi.org/10.2139/ssrn.1587372>.

²³ Jorge Larson Guerra, “Geographical Indications, In Situ Conservation and Traditional Knowledge.” *Geneva, Switzerland: International Centre for Trade and Sustainable Development* (2011), https://doi.org/10.7215/IP_PB_20110211.

tives: the legal status of materials, the freedom to use materials, and the availability and accessibility of materials. These will be discussed in turn.

A. THE LEGAL STATUS OF MATERIALS

The public domain consists of resources free from IP rights, that is, every intellectual product that was never or no longer is under IP protection.

This can include:

1. Material that was ineligible for protection in the first place, for example, material of insufficient originality to qualify for copyright protection, or an invention that did not fulfill the conditions of patentability;
2. Material “freed” by invalidation or expiry of an IP right;
3. Material that was eligible for protection but, in the case of industrial property, in respect of which protection was not applied for.

B. THE FREEDOM TO USE

Public domain material is material that is free or available for any member of the public to use for any purpose without having to obtain the consent or permission of a right owner and without charge. There have been several propositions that this supports greater innovation than proprietary material.

C. AVAILABILITY AND ACCESSIBILITY OF MATERIALS

Access of materials in the public domain range from complete access to restrict access subject to permissions. Trustworthiness of use of information is the basis of making available public domain materials. Therefore, public domain material is not always free from any cost or encumbrances. Access to some public domain material may depend on laws that protect confidential information, trade secrets/know how. Technical protection measures utilise to protect against unauthorised copying of information. .

It must be noted that there is an important distinction in the context of TK is that between TK being in the “public domain” and TK being “publicly available”. The term public domain, which is used to indicate free availability, has been taken out of context and applied to TK associated with genetic resources that is publicly available. The common understanding of publicly available does not mean available for free but that there is a condition to impose mutually agreed terms such as paying for access.

With the introduction of a Glossary on TK by the WIPO, there has been a harmonious interpretation of the definitional aspects of TK. While one notion

supports the fact that the unrestricted and general use of TK has helped in its dissemination, another one emphasises on the need for consent principles to be followed for access of TK associated with genetic resource. With the Access and Benefit Sharing regime in operational it is imperative that not only prior informed consent form a TK holder but also executing an agreement for benefit-sharing²⁴”.

XII. RELATIONSHIP BETWEEN THE PUBLIC DOMAIN AND CUSTOMARY AND INDIGENOUS LAWS

From the perspective of indigenous peoples and local communities, the public domain operates to exclude TK and TCEs from protection and can be used to justify their misappropriation. As indigenous cultures tend not to make property/non-property distinctions, the concept of public domain is alien to them. Customary laws provide rules for the sharing of TK and TCEs within a community. Hence, even the use of TK is common, the need to know and/ access is defined under the community rules. Indigenous cultural heritage represents several practices that are secret and have been used in this way from time immemorial. Respecting TK and TCEs of communities is an important requirement for their responsible use.

XIII. THE VALUE OF THE PUBLIC DOMAIN

A strong justification for the ‘common good’ nature of TK and TCEs is that it has been the source of development of numerous products as well as processes for human value. Public domain has been the main source for innovations. By overprotecting cultural expressions, public domain diminishes, leaving fewer works to build on²⁵. The recent past has demonstrated to us the fragility of human life compelling the need to relook for how TK and TCEs have been involved in sustaining human life and well- being. Not surprising is therefore the call for mainstreaming TK for human well-being. Revisiting the context of public domain calls for the need to foster TK and TCEs and expand their scope for value addition to human life. Recent international discussions on repatriation of TK is expected to create an opportunity for stakeholders

²⁴ The experts at the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing distinguished the terms “public domain” and “publicly available” with special reference to TK associated with GRs.

²⁵ BananaIP Reporter, “National IPR Policy: Traditional Knowledge Related Objectives,” accessed May 24th 2016, <https://www.bananaip.com/ip-news-center/traditional-knowledge-ipr-policy-2016/>

with a ‘shared goal’ to enrich the public domain.

XIV. TRADITIONAL MEDICINAL KNOWLEDGE

In India, the national policy on traditional and alternative medicine was introduced in 1940 in the form of Drug and Cosmetic Act, 1940 and Drug and Cosmetic Rule 1945. Traditional Indian System of Medicine and updated Drug and Cosmetic Act in 1959 by the Government of India. Separate Chapter related to Ayurveda, Unani and Siddha drugs was inserted by the act 13 of 1964 in the year 1969²⁶. In 2006 and 2008 guideline for evaluation and analysis of drugs under ISM was given under Drug and Cosmetic Rule 1945. The framing and implementing different regulations for Ayurveda, Siddha and Unani in ISM is involved through Central Council of Indian Medicine, 1970²⁷. In 2012, Sowa Rigpa system of medicine is incorporated in the CCIM. With the objective to develop the ISM, Department of Indian Medicine and Homeopathy was formed. In 2013, this Department was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), and in 2014 separate ministry on AYUSH was formed²⁸.

XV. MINISTRY OF AYUSH

Department of AYUSH concentrates on the overall governance, regulation, education, growth and development of ISM in the India and abroad. The department has few subordinate offices, pharmacopoeia laboratories, professional, several autonomous bodies in the form of research councils, national institutes, academy and hospitals²⁹. National Policy on Indian Systems of Medicine & Homoeopathy was introduced in the year 2002. Major objective of this policy are:

1. It provides policy support to research, drug standards regulation and

²⁶ Daniel Gervais, “Traditional Innovation and the Ongoing Debate on the Protection of Geographical Indications,” *Indigenous Peoples’ Innovation* (2012), <https://www.jstor.org/stable/j.ctt24hfgx.12>.

²⁷ Ajeet Mathur, “Who Owns Traditional Knowledge,” *Indian Council For Research On International Economic Relations* (2021), accessed January 16th 2021, <https://icrier.org/pdf/WP96.pdf>.

²⁸ Shivani Singhal, “Geographical Indications and Traditional Knowledge,” *Journal of Intellectual Property Law and Practice* (November 2008): 3, <https://doi.org/10.1093/jiplp/jpn160>.

²⁹ Kirti Singh, “Geographical Indication as a Tool for Protection of Traditional Knowledge with Special Reference to Protection of ‘Cashmere’ in Kashmir,” SSRN Scholarly Paper ID 2115257. Rochester, NY: Social Science Research Network (2012), <https://doi.org/10.2139/ssrn.2115257>.

enforcement, financing, education of traditional medicine systems.

2. To ensure the availability and genuine of raw drugs was required by pharmacopeial standards to help improve quality of AYUSH drugs, for domestic and/or export purpose.
3. Utilize the AYUSH to endorse good health and spread out the outreach of healthcare to our people through preventive, mitigative, promotive and curative approaches.
4. To offer full opportunity for the expansion and development of ISM and utilization of the potentiality, strength and revival of their glory.
5. Incorporate AYUSH in healthcare delivery system and national programmes and to ensure the best possible utilization of huge infrastructure of hospitals, dispensaries and physicians.

Generally, the biological resources are found in the developing countries in plenty and meant for the welfare of local communities as well as the entire world. The contradiction is that the finished products made out of these biological resources by bio-prospecting using TMK as the base knowledge, such as drugs are, are then not available to the poor countries and communities³⁰. The base Traditional Medicinal Knowledge is not only not acknowledged but is de-legitimised, and the communities tend to lose their traditionally accessible resources due to cost escalation³¹.

Biodiversity can be considered as the foundation for human health as it underpins the functioning of the ecosystems on which we depend for our food and fresh water; aids in regulating climate, floods and disease; provides recreational benefits and offers aesthetic and spiritual enrichment. Biodiversity also contributes to local livelihoods, to both traditional and modern medicines and to economic development³².

All human health ultimately depends on ecosystem services that are made possible by biodiversity and the products derived from them. While the inter-linkages between biodiversity, ecosystem services and human health are

³⁰ Jena, Pradyot, Chuthaporn Ngokkuen, et al., "Geographical Indication Protection and Rural Livelihoods: Insights from India and Thailand," *Asian-Pacific Economic Literature* (May 2015.):174–85, <https://doi.org/10.1111/apel.12092>.

³¹ Gopalakrishnan, N., Prabha Nair, and Aravind Babu, "Exploring the Relationship Between Geographical Indications and Traditional Knowledge," *Working Papers eSocialSciences* (2017), <https://ideas.repec.org/p/ess/wpaper/id12352.html>.

³² Gopalan, Raguvaran, and Sindhu Sivakumar, "Keeping Cashmere in Kashmir: The Interface between GI and TK," https://www.jstor.org/stable/pdf/j.ctt24hfgx.12.pdf?ab_segments=0%252Fbasic_SYC-5187_SYC-5188%252Fcontrol&refreqid=excelsior%3A76a0aad38510bdc988d642a1b15cab2d.

inherently complex, inter-disciplinary research is aiming to develop a more thorough understanding of these essential relationships³³.

XVI. THE INDIAN SYSTEMS OF MEDICINE – POLICIES AND PROGRAMMES

Through Forest Laws and Laws regulating access to biodiversity there exist laws for protecting and conserving medicinal plant genetic resources.

A. THE WILD LIFE (PROTECTION) ACT, 1972 (AMENDED IN 2002)

Through a network of ecologically important protected areas, restricts carrying out any industrial activity inside these protected areas and co-operative management through community reserve committees and conservation reserve management committees.

B. THE FOREST CONSERVATION ACT, 1980 (AMENDED IN 1988)

It regulates the de-reservation of forests or use of forest land for non-forest purposes without the prior approval of Central Government.

C. THE NATIONAL FORESTRY POLICY (2016 DRAFT)

It provides for community participation at the Gram Sabha (Village Council) level for management of forests.

The National Wildlife Action Plan 2017-2031 includes some key features such as Use of mobile technology to develop ‘Digital Field Guides’ for easy identification of various wildlife goods and their derivatives, conservation of threatened species of flora especially local endemics and highly traded species.

D. THE NATIONAL ENVIRONMENT POLICY, 2006

It calls for enhancing and conserving environmental resources which includes biodiversity, encouraging cultivation of traditional varieties of crops and traditional water conservation efforts, unlocking the value of genetic diversity. It calls for harmonizing the Patents Act 1970 with Biological Diversity Act 2002.

³³ Sehgal, Diganth Raj, “Role of International Forums in Protection of Traditional Knowledge,” <https://blog.iplayers.in/role-international-forums-protection-traditional-knowledge/>, accessed July 26th 2020.

The National Medicinal Plants Board undertakes a wide range of duties for quantification of medicinal plants for commercial use, inventorisation and medicinal plants conservation. India has adequate regulatory bodies for protection of medicinal PGRs through access control, research and development for improved medicinal PGRs, gene banks.

XVII. NATIONAL IP POLICY – ENABLING MECHANISM FOR TRADITIONAL KNOWLEDGE THROUGH GEOGRAPHICAL INDICATIONS

With a vision to stimulate creativity and innovation and to promote advancement in Arts and Culture, Science and Technology, Traditional Knowledge and Biodiversity Resources, India approved its first ever IPR policy³⁴.

The following positive considerations are provided with respect to Traditional Knowledge:

- a. It specifically aims at creating public awareness relating to Traditional Knowledge, Genetic Resources, Traditional Cultural Expressions, Folklore and Geographical Indications by reaching out to IP generators and holders, more specifically in the rural and remote areas, with an aim to target small businesses, farmers/ plant variety users, holders of traditional knowledge, traditional cultural expressions and folklore, designers and artisans. It aims to shift how knowledge is viewed and valued. Makes efforts to transform knowledge into IP assets by exhorting monetization of knowledge which has never been the norm in India.
- b. The IPR Policy seeks to stimulate generation of IPRs, with respect to traditional knowledge specifically by emphasizing on conducting activities for promotion of traditional knowledge with participation of holders of such knowledge.
- c. Considers provisions to expand the ambit of Traditional Knowledge Digital Library (TKDL) for its utilization in further R&D and expansion of the ambit of TKDL to include other fields besides Ayurveda, Yoga, Unani and Siddha for which it is currently restricted to. In addition to expansion of TKDL domain it also explores options for public research institutions to be allowed access to TKDL for further

³⁴ “Geographical Indications, In Situ Conservation and Traditional Knowledge.” Geneva, Switzerland: International Centre for Trade and Sustainable Development. https://doi.org/10.7215/IP_PB_20110211.

R&D, and makes room for exploring the options of providing access to TKDL for further R&D by private sector by placing necessary safeguards to prevent misappropriation.

- d. Provides for documentation of oral traditional knowledge and considers providing support and incentives for traditional knowledge holders for furthering the knowledge systems.
- e. Recognises India's rich diverse form of traditional medicinal knowledge which includes well developed systems like Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa and Homeopathy. Further the policy also states the need to protect such knowledge, be it oral or in codified form, from misappropriation, while providing space and environment for dynamic development of traditional knowledge for benefit of mankind. To achieve this objective, the Policy lays emphasis on continued active and constructive engagement in the deliberations at various international forums to develop legally binding international instruments to protect Traditional Knowledge (TK), Genetic Resources (GR) and Traditional Cultural Expressions (TCE) and exploring of possibility to determine the appropriateness and extent of application of the existing laws to protect TK, GR and TCE, in addition to proposition of changes if required to them.
- f. Seeks to modernize and strengthen service-oriented IPR administration lays emphasis on steps to include TKDL as a part of PCT minimum documentation.
- g. Consider establishing close cooperation between IPOs and creating a common web portal for ease of access to statutes, regulations, and guidelines and for better coordination.
- h. Consider establishing effective coordination between its office and National Biodiversity Authority to enable harmonious implementation of guidelines relating to grant of patents on inventions using biological resources and associated TK.
- i. Strengthen the enforcement and adjudicatory mechanisms for combating IPR infringements and pursue incidents of misappropriation of TK, GR and TCE in other countries vigorously.

Effective implementation of the Policy can achieve wonders and lay ground work for myriad medical and agricultural break-through based on the existing rich Traditional Knowledge and emancipation of Traditional Knowledge holders. IPR policy is a positive move by the government towards build-

ing an effective IPR regime³⁵.

XVIII. CONCLUSION

Traditional Knowledge is integral to the identity of most local communities. It is a key constituent of a community's social and physical environment and, as such, its preservation is of paramount importance. Attempts to exploit TK for industrial or commercial benefit can lead to its misappropriation and can prejudice the interests of its rightful custodians. The preservation, protection and promotion of the TK-based innovations and practices of local communities are particularly important for developing countries. Their rich endowment of Traditional Knowledge and Biodiversity plays a critical role in their health care, food security, culture, religion, identity, environment, trade and development. Yet, this valuable asset is under threat in many parts of the world.

Documenting and digitizing Traditional Knowledge-related information in the form of a TKDL is proving to be an effective means of preserving Traditional Knowledge and of preventing its misappropriation by third parties. India is a pioneer in this field. There are concerns that this knowledge is being used and patented by third parties without the prior informed consent of Traditional Knowledge holders and that few, if any, of the derived benefits are shared with the communities in which this knowledge originated and exists. Such concerns have pushed TK to the forefront of the international agenda, triggering lively debate about ways to preserve, protect further develop and sustainably use Traditional Knowledge.

³⁵ Susy Frankel, "The Mismatch of Geographical Indications and Innovative Traditional Knowledge," *Prometheus* (2011): 29 (3): 253–67, <https://doi.org/10.1080/08109028.2011.629872>.

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