TRADITIONAL KNOWLEDGE AND PATENT PROTECTION IN INDIA: EXAMINING THE LEGAL DIMENSION

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ABSTRACT

In India, traditional knowledge (TK) is collective held, transmitted through generations, and intimately linked to biological resources, whether it is in the fields of medicine, agriculture, or ecology. Due to its financial potential, it has become a target for biopiracy, which involves obtaining patents elsewhere for usage that Indian tribes have been using for generations. This paper investigates the extent to which TK is shielded against misuse by Indian law and if it provides communities with any benefits beyond defense. It integrates a comparative study of Peru, Philippines, and Brazil. It contends that although India has developed a strong defense, a right has not been established. Wrongful patents are blocked by sec. 3(p), the oral- Knowledge grounds in sec. 25 & 64, Traditional knowledge Digital Library and Benefit-Sharing is managed by the state and has been relaxed for codified information by the 2003 amendment and provides communities with no independent recourse. Community custodianship, tiered registers based on People's Biodiversity Register, consent with mutually agreed terms, direct standing and civil remedies, and a derivation test that distinguishes genuine invention from traditional knowledge are all components of the proposed sui generis statutes, which integrates rather than replaces current law.

Keywords: Traditional knowledge, Biopiracy, Patent Act 1970, Biological Diversity Act 2002, Traditional Knowledge Digital Library, Benefit-Sharing, Sui-Generis Protection.

INTRODUCTION

The collective wisdom, customs, and living legacy of indigenous peoples, tribal, and local communities that are passed down from one generation to the next is known as traditional Knowledge, or TK.[1] It comprises knowledge relevant to general healthcare, agriculture, food production, biodiversity, and the sustainable use of natural resources. Beyond its cultural relevance, traditional knowledge has great scientific ecological and economic value, notably in biotechnology, medicines, and agriculture. However, collectively generated traditional knowledge is frequently kept outside the purview of traditional intellectual property protection due to the historical evolution of intellectual property law, which largely priorities individual ownership and private rights.[2] As a result, such information has often been seen as belonging to the public domain and used for commercial and scholarly purposes without giving its custodian proper credit or a fair portion of the benefits. Concerns about stealing traditional knowledge, or "biopiracy", have grown as a result of the quick development of technology and the growing commercialization of biological resources. Without getting the proper permission, giving credit to the initial knowledge holders, or guaranteeing fair benefit sharing, research organizations, businesses, and other groups may use information conserved by indigenous groups to create goods and procedures. Such activities raise issues not just about financial abuse but also about preservation of culture, community liberties, and the marginalization of traditional communities., The preservation of TK is crucial for sustainable growth, biodiversity conservation, and community empowerment since many indigenous and tribal populations rely on it for their healthcare, livelihoods, food security, and interaction with the natural environment.

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[1] WIPO, Traditional Knowledge, World Intellectual Property Organization
[2] The Convention on Biological Diversity,1992, art.8(j).
[3] Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity: Seeds and Plants varieties 2-4 (Earthscan 2000).

for sustainable growth, biodiversity conservation, and community empowerment since many indigenous and tribal populations rely on it for their healthcare, livelihoods, food security, and interaction with the natural environment.

The Patent Act[4] in India offers certain protections against the unapproved use of traditional knowledge. Inventions that are fundamentally traditional knowledge or that only include the aggregation or replication of known qualities of traditionally known components are not eligible for patent protection under the law. Additionally, it offers procedures for opposing patent applications or awarded patents on certain legal grounds, as well as for revealing the source and geographical origin of biological material. Additionally, the Traditional knowledge Digital Library (TKDL) which was created by the Ministry of AYUSH and the council of scientific and Industrial Research (CSIR) [5], acts as a defensive mechanism by recording traditional medical knowledge and making it available to patent examiner in order to help stop the granting of patents over existing knowledge. However, these measures do not, by themselves, create an extensive system of positive protection that acknowledge the collective liberties of knowledge-holding communities or ensure their participation in commercial benefits; rather, they focus on preventing inappropriate patent grants.

The problems with neem, turmeric, and Basmati rice[6] demonstrate how challenging it is to protect biological resources and traditional knowledge under the current intellectual property laws. These illustrations show how important it is to demonstrate prior art, acknowledge the contributions of traditional societies, and distinguish claims based primarily on pre-existing knowledge from genuine invention. There are still concerns about the active participation of local populations, the preservation of oral and undocumented knowledge, and the fair distribution of benefits resulting from commercial utilization, even though India's current legal and institutional frameworks have been beneficial in addressing some cases of biopiracy. Another challenge is ensuring that communities may benefit from truly innovative discoveries made with their traditional knowledge without undermining legitimate innovation.

Given this, the current study critically assesses the extent to which Indian patent law safeguards traditional knowledge, focusing on relevant statutory provisions, the role of the Traditional

[4] The Patents Act, No. 39 of 1970, § 10(4)(d).
[5] Council of scientific & Industrial Research & Ministry of AYUSH, Traditional knowledge Digital Library.
[6] WIPO, Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expression.

Knowledge Digital Library, and notable instances involving traditional biological resources. It also considers particular tactics employed in countries like Peru, the Philippines, and Brazil in order to explore how Through this comparative analysis, the study evaluates if further modifications, such as a suitable sui generis system, are necessary or whether the existing Indian framework adequately addresses the concerns of indigenous and tribal groups. Investigating a more inclusive framework that prohibits misappropriation, recognizes community contributions, promotes equitable benefit sharing, and allows traditional knowledge holders to participate in the social and economic benefits that arise from the continuous application and advancement of their knowledge is the primary objective. Community engagement and collective goals may be incorporated into legal protection.

CONCEPTUAL FOUNDATION

What Counts as Traditional Knowledge

Traditional Knowledge is neither specifically defined by Indian law nor has been widely recognized legal meaning. In general, WIPO defines it as the information, abilities, inventions, and customs that are created and passed down within communities as a component of their cultural identity. In a similar vein. Article 8(j) of the convention on Biological Diversity acknowledge indigenous and local knowledge and customs that are pertinent to the preservation of biodiversity. In the lack of a formal definition under the Patent Act 1970, the Madras High Court in Zero Brand Zone looked to WIPO and UNESCO documents when evaluating TK.[7] As a result, Indian Courts have, in certain cases, relied on international materials.

In general, there are two types of TK in India: codified and Uncodified. Classical systems like Ayurveda, Siddha, Unani, and Yoga have codified TK. On the other hand, pastoral, agricultural, and forest- dwelling groups conserve uncodified TK. Through oral traditions and firsthand knowledge of plants, seeds, soil, and animals, this disparity has legal implications since orally conveyed information may be more challenging to record, verify, or ascribe to specific populations, whereas written Knowledge is easier to identify and prove as previous art.

Features that Strain Patent Law

TK is often collaborative, intergenerational, and dynamic, which sets it apart from traditional

[7] M/S Zero Brand Zone vs. Controller of Patents & Designs,2024 SCC OnLine Mad 4159.

patentable ideas. It develops across centuries rather than on a single invention date, is frequently linked to communities rather than a single creator, and changes continuously. As a result, its nature is to not completely accommodated by patent law, which is predicted on individual inventorship, recognized innovations, and short protection periods. Communities may be exposed to commercial appropriation if TK is seen as a part of the public domain.

Biopiracy, and Defensive and Positive Protection

The illegal use or commercial exploitation of biological resources or related TK without appropriate authorization or benefit- sharing is known as biopiracy. Both incorrect patent claims and unauthorized access may be involved; these are addressed by patent law and access and benefit- Sharing legislation, respectively.

WIPO makes a distinction between positive protection, which allows communities to govern, license, and profit from their knowledge, and defensive protection, which stops false intellectual property claims by proving TK as previous art. Therefore, both strategies are necessary for effective protection.

PATENT LAW DEFENCES AND THE TKDL

What are the three classic Disputes taught

Council of scientific and Industrial Research (CSIR) was able to show earlier Indian Knowledge through existing documents; the turmeric patent[8] case served as an example of the value of documentary proof. Similar to this, a European patent for a fungicidal technique based on neem that was awarded in 1994 to the US Department of Agriculture and *W.R. Grace* was challenged in 1995 by a number of NGOs based on evidence of its traditional use in India. Due to a lack of innovative steps, the patent was invalidated in 2000, and the ruling was maintained on appeal in 2005. A 1997 US patent on basmati lines and grains that was awarded to RiceTec[9] was at the center of the basmati controversy. RiceTec renounced the most of its general claims in 2001 in response of India challenge in 2000, leaving protection restricted to particular claims.

The issue also brought attention to the importance of trade law, plant variations, and

[8] Council of Scientific & Industrial Research v. University of Mississippi Medical Centre, U.S.Patent No. 5,401,504 (1995)
[9] RiceTec, Inc.,U.S. Patent No. 5,663,484 (issued sep.2,1997)

geographical designations outside of patent.[10]

Three key lessons may be learned from these disagreements. First, as the neem proceedings demonstrate, contesting patents after they are granted may be time-consuming and resource intensive. Second, rather than acknowledging communities as holders of enforceable rights over their knowledge or guaranteeing them a portion of economic advantages, the results mostly relied on proving previous art. Third, in order to identify recorded traditional knowledge before improper patent protection is given, these experiences prompted India to bolster preventative procedures during the patent assessment stage, especially through the Traditional Knowledge Digital Library (TKDL).

Section 3(p) and its Judicial Reading

The Joint Parliamentary committee on the Patent (second amendment) Bill, 1999, recommended the introduction of sec.3(p) in the Patent Act.[11] The provision excludes from patentability an invention that is, in effect, traditional knowledge or merely an aggregation or duplication of known properties of traditionally known components. The Provision is significant because it focuses on the substance of the claimed invention rather than merely its particular form or manner of presentation.

However, because section 3(p) does not define "traditional knowledge" or "traditionally known components," its application is still ambiguous. The Madras High Court examined a patent application pertaining to an eco-friendly lam made of Panchagavya, neem, lemon, and peepal leaves in M/s Zero Brand Zone v. Controller of Patent & Designs. Sections 3(d), 3(e), and

3(p)[12] were among the reasons the application was denied, and the court supported the decision. The ruling illustrates how section 3(p) may be applied to discoveries pertaining to domestic and agricultural operations in addition to traditional medical expertise.

The ruling also emphasizes the need for further legislative and judicial clarification on the conditions under which an invention may be deemed to be "in effect" based on TK. It is especially crucial to distinguish between 3(d) and 3(p). While section 3(d) deals with specific

[10] Government of India, Basmati Rice: India's objections to RiceTec Patent, Ministry of Commerce and Industry (2000)
[11] Department-Related Parliamentary Standing Committee on Commerce, *Second Report on the Patents (Second Amendment) Bill, 1999*, Parliament of India (2000).
[12] The Patents Act, No. 39 of 1970, §§ 3(d), 3(e), 3(p).

novel forms of known compounds and, where relevant, calls for increased therapeutic efficacy, section 3(p) deals with subject matter that is mostly taken from existing traditional knowledge. Therefore, in cases where the claimed technical contribution is truly unique and different from the underlying traditional knowledge, the simple utilization of conventional biological resources should not be sufficient to prevent patent protection.

Opposition, revocation and disclosure

Sec.3(p) is supplemented by the Patent Act through a number of procedural protections. A patent may be challenged under sec. 25(1)(k) & 25(2)(k) if claimed invention has been anticipated by oral or other information that is accessible with in a local or indigenous community in India or elsewhere.[13]

The disclosure should include information about the sources and geographical origin of the biological materials used in the invention.[14] Misrepresentation or lack of such information can be considered grounds for invalidation of a patent or for contesting its grants. Furthermore, even if this information is not in the public domain, prior use of it in India might be relevant to the evaluation of the invention's novelty and validity.

Both provisions recognize that undocumented community knowledge is relevant prior art and permit any third party to contest a patent, without needing any action from the community itself.

The Traditional Knowledge Digital Library

After the turmeric and neem patent conflicts, CSIR collaborated with the Department of Indian systems of Medicine and Homeopathy (now the Ministry of Ayush) to build the Traditional Knowledge Digital Library (TKDL) in 2001. Its goal is to make recorded TK accessible as searchable prior to art while a patent is being examined. Classical texts on Ayurveda, Unani, Siddha, Yoga, and Sowa Rigpa are digitized, categorized and translate into English, German, French, Japanese, and Spanish. Under some agreements, patent offices- such as the US patent and Trademark offices and the European patent office- can access the database.

By assisting patent examiner in identifying existing TK prior to granting exclusive rights, the TKDL has strengthened India's defensive protection. However, its coverage is primarily

[13] The Patent Act, 1970 (Act 39 of 1970), §§ 25(1)(k), 25(2)(k). [14] The Patent Act,1970 (Act 39 of 1970) § 10(4)(d).

restricted to codified knowledge and does not fully address oral and community- held practice, its state-controlled structure also provides limited direct community participation in documentation and use; and its efficacy depends on access by participating patent offices and accurate identification of relevant knowledge during examination. Since the TKDL does not grant communities ownership, consent, attribution, or benefit-sharing rights, it should be seen as a defensive tool that supplements rather than replaces more comprehensive legal protection for TK. As such, it is an important preventive mechanism against inappropriate patent claims.[14]

ACCESS AND BENEFIT- SHARING UNDER BIOLOGICAL DIVERSITY ACT

In addition to the Biological Diversity Act of 2002 that is regulated by the NBA, the State Biodiversity Boards and BMCs, there exists an additional regulatory regime relating to the regulation of biological resources and associated traditional knowledge. Normally, foreign individuals and entities that wish to have access to Indian biological resources and their associated knowledge for scientific or commercial reasons require the approval of the NBA. As for the Indian firms that access biological resources for commercial exploitation, there exists a different regulatory regime that requires the notification of the concerned State Biodiversity Board.[15] The Biological Diversity Act of 2002 also sets up an ABS regime under which benefits may be in the form of financial payments, technology transfer, joint ownership of IPRs, research and other mutually negotiated benefit-sharing regimes. Individual or community benefit claimants can be those who conserve biological resources and have associated traditional knowledge.

The Act includes provisions aimed at the protection and conservation of traditional knowledge.

Where there is any application of intellectual property rights from other countries based on Indian biological resources or traditional knowledge, the National Biodiversity Authority (NBA) has the power to take suitable steps to ensure the interests of India. It also includes the establishment of the Biodiversity Management Committees (BMCs) and the People's Biodiversity Registers (PBRs) for the documentation of Indian biological diversity along with its traditional knowledge.

[14] Shaafi Naturcure LLP v. Assistant Controller of Patents and Designs C.A.(COMM.IPD-PAT) 109/2022 (2026: DHC:5157).
[15] Dabur India Limited v. National Biodiversity Authority, Appeal No. 54 of 2022 (SZ)

Moreover, it makes it obligatory for the Central Government to take necessary steps for the conservation and protection of the Indian biological diversity and traditional knowledge through registration of the same and the adoption of the sui generis system.

In order to improve access to biological resources and encourage study and economic use, the Biological Diversity (Amendment) Act, 2023[16] made a number of adjustments. The updated framework alters the regulatory requirements applicable to distinct types of users and allows for certain instances in which approval or registration requirements may apply. Additionally, it discusses access to related traditional information and establishes exclusions for specific groups, such as grown medicinal plants, certified AYUSH practitioners, and some types of codified traditional knowledge, subject to relevant circumstances. Even though these exemptions may reduce regulatory restrictions and allow for legal research and usage, they raise concerns regarding benefit sharing with communities that have historically produced and retained such knowledge. Numerous initiatives have been both documented and codified. Additionally, terms like "sustenance and livelihood" and "codified traditional knowledge" would need to be explained to avoid ambiguity in their applicability. As a result, the amendment emphasizes the continued necessity for effective measures to defend genuine community interests and prevent the theft of biological resources and traditional knowledge. Additionally, it is an effort to reconcile the simplification of regulations with the advancement of research and legitimate commercial use.[18]

The example of India implementing the Nagoya Protocol is one of many examples showing how ABS systems are becoming increasingly institutionalized. Specifically, India submitted its first National Report regarding the Nagoya Protocol on 27 February 2026. The reporting period for this report is from November 2017 to December 2025, and the report documents 276,000 Biodiversity Management Committees and 12,830 ABS approvals. The amount of about ₹216.31 crore was generated through NBA clearances, out of which, ₹139.69 crore was distributed in favor of claimants, who include local communities and owners of TK. It is noted further in the report that India has distributed 3,556 certificates of international repute, which constitute more than 60% of the total number of certificates distributed worldwide at the time of reporting. It can be understood from these statistics that there is considerable institutional effort on part of the country in the implementation of the ABS regime, though the success of

[16] The Biological Diversity (Amendment) Act, 2023 (Act No. 10 of 2023) [18] D.C.M. Shriram Ltd. V. National Biodiversity Authority.

the regime depends on community participation and benefit-sharing.

LANDMARK BIOPIRACY DISPUTES

1. Turmeric

Patent dispute on turmeric is extensively referenced in academic analyses on the subject of Indian Traditional knowledge. The United State patent filed for the application of turmeric in wound healing was contested by India, as they were able to prove, using documentary evidence, that the particular medical application was already known.[17] After the patent was re-examined, the patent was canceled**.** Importantly, what made the case important is not who had filed the patent but rather the core of the issue involved, "in the case demonstrate the difficulty of identifying traditional knowledge as prior art when relevant information was contained in traditional texts and literature that were not readily accessible or understandable to patent examiners."

This case played an important role in a policy trend leading to the creation of the Traditional Knowledge Digital Library (TKDL). According to WIPO, India's success in contesting the turmeric patent is one of the events contributing to the creation of the database.

2. Neem

The case of neem concerned itself with the patenting of the fungicidal nature of neem. In this case, arguments concerning the customary use of neem preparations were presented by the Indian and the European objectors. As a result, the patent was eventually revoked. This example shows how the customarily used practice may carry a lot of significance as far as the validity of a patent is concerned.[18] It additionally shows the costs and complications involved in contesting a patent after the examiners failed to consider the existing prior art.

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[17] *Cohly et al.*, U.S. Patent No. 5,401,504 (granted Mar. 28, 1995), re-examination requested by Council of Scientific and Industrial Research (CSIR), India, Oct. 28, 1996; U.S. Patent & Trademark Office, Re-examination of U.S. Patent No. 5,401,504 (1997) (rejecting the claims relating to the use of turmeric for wound healing on the basis of prior art demonstrating that such use was already known in Indian traditional medicine); World Intellectual Property Organization (WIPO), *Intellectual Property and Genetic Resources in the Life Sciences: Use of Turmeric in Wound Healing* (explaining that the patent was subsequently found invalid after documentation, including ancient Sanskrit texts demonstrated that the claimed use constituted known traditional knowledge).

[18] *Method for Controlling Fungi on Plants by the Aid of a Hydrophobic Extracted Neem Oil*, Case No. T 0416/01, EPO Board of Appeal (Mar. 8, 2005). [21] *RiceTec, Inc.*, U.S. Patent No. 5,663,484, Basmati Rice Lines and Grains (U.S. Patent & Trademark Office Sept. 2, 1997).

3. Basmati Rice

The Basmati rice case is one such example of cases concerning issues of protection of traditional knowledge and biological resources. In September 1997, the United States Patent and Trademark Office awarded a patent to RiceTec[21] in relation to varieties and breeding methods of Basmati rice, which is an aromatic variety of rice which has been traditionally cultivated in the Indian sub-continent including India and Pakistan. The issuance of the patent was highly criticized due to the fact that the Basmati rice has been cultivated and developed by farmers in the region over several generations. The Government of India has objected to some parts of the patent on the grounds that there were issues relating to international regimes of traditional knowledge, biodiversity and access to biological resources. Similarly, the South Asia Commission on Economic and Social Policy too pointed out that there were rights and interests of India and Pakistan related to Basmati rice which the patent violated. The Basmati case thus brings up a wider issue within the regime of patents; while traditional varieties and knowledge might be in existence for several years, new developments which can be brought about through breeding or crossbreeding of these varieties and knowledge can be claimed as inventions.

4. Maca

Another illustration of the difficulties in preventing biopiracy of traditional knowledge is the Maca case. Two US businesses received patents in 2001 for extracts from the Andean plant Maca, which had long been utilised by the indigenous population for fertility and sexual health, in response to the increasing commercial interest in items related to sexual health. The patents were based on the use of the patents. The case highlights a more general worry that current intellectual property laws could not always offer enough defence against the unapproved commercial exploitation of traditional knowledge.Without properly acknowledging the contribution of the communities that have maintained and cultivated such knowledge, traditional knowledge may be used as a foundation for scientific study and the creation of commercial products. The communities involved may receive little or no part of the ensuing economic gains when patents are awarded based on pre-existing traditional knowledge, and they may still be in danger of marginalization and theft. Indian patent law tackles such issues through a number of precautions that concern biological resources and traditional knowledge. In accordance with the Indian patent law, any patent application needs to include the sources of

the biological resource and its geographical location.[19] Failure to do so can result in opposition to the patent or even cancellation of the already issued patent. In order to determine whether an invention is truly new, the law also acknowledges existing local knowledge, particularly knowledge that has been passed down orally, as possibly relevant prior art. This makes it possible for revocation. Additionally, patent protection does not apply to inventions that just replicate or aggregate recognised qualities of previously known components, or that simply embody conventional knowledge. Together, these clauses aim to stop patents from being granted for inventions that don't really add anything new to what traditional and local communities already know.[20]

WHERE THE FRAMEWORK FALLS SHORT

Proof and the paradox of documentation

Even if oral and community-held information is recognised under the Patents Act as relevant prior to art, it might be challenging to prove its existence, substance, origin, and community affiliation prior to the pertinent priority date. For communities, this poses a serious evidential difficulty.[21]

By recording codified knowledge and providing it to partner with patent offices under specified circumstances, the TKDL tackles this issue. However, oral and uncodified traditions are not completely covered. "Although People's Biodiversity Registers (PBRs) provides a decentralized mechanism for documenting biological resources and associated traditional knowledge, the patent does not specifically designate PRBs as a separate class of statutory prior art or specify how their contents may be relied upon in patent proceedings".[22]

Documentation also creates a practical dilemma. Information recording can increase its legal visibility and help avoid bogus patent claims, even though more disclosure may increase the likelihood of illegal use. Therefore, community involvement, confidentiality, evidential

[19] Patents Act, 1970, § 25(1)(k), § 25(2)(k) (permitting opposition to a patent where the invention has been anticipated by knowledge, oral or otherwise, available within a local or indigenous community in India or elsewhere); id. § 64(1)(q) (providing a corresponding ground for revocation of a patent).
[20] *Dimminaco AG v. Controller of Patents & Designs*, 2002 SCC OnLine Cal 844, AIR 2002 Cal 121 (holding that a product containing a living organism may constitute a "manufacture" or "substance" capable of patent protection, provided the statutory requirements of patentability are satisfied).
[21] The Patents Act, 1970, (Act No. 39 of 1970), §§ 25(1)(k), 25(2)(k), 64(1)(q).
[22] *M/s Zero Brand Zone v. Controller of Patents & Designs*, O.A. No. 32 of 2020/PT/CHN, Madras High Court, July 5, 2024.

significance, and abuse prevention must all be balanced in an effective recording system.

Consultation is not consent, and communities cannot sue

The NBA and SBA must confer with biodiversity Management com However, community approval or agreement does not necessarily follow consultation, as stated in Article 7 of the Nagoya Protocol. According to section 41(2) of the Biological Diversity Act,[23] communities often engage as benefit claimers rather than as direct parties to access agreements, and the Act does not expressly give them autonomous standing to pursue remedies for the misuse of their TK Communities (BMCs**)**

A useful contrast is provided by the Protection of Plant Verities and Farmers Rights Act, 2001, which permits individuals or organizations to submit benefit-sharing claims on behalf of villages or local communities. This suggests that representative standing is allowed by Indian law. A similar method might enhance TK protection by allowing communities or appointed representatives to make direct claims. Clear protocols are also necessary to resolve disputes when the same information is shared by multiple organizations or geographical regions.[24]

THE INTERNATIONAL FRAMEWORK

India's approach to TK is influenced by three main strands of international law. The convention on Biological Diversity (CBD) is the first. Article 15 links access to prior informed consent and mutually agreed terms while acknowledging nations' sovereign rights over genetic resources. It mandates that states, pursuant to national law, safeguard and protect indigenous and local communities' knowledge and customs and encourage their broader use with knowledge holders' consent and participation, along with fair benefit-sharing.[25]

This framework is further developed by the Nagoya Protocol,2010, which was approved by Indian in 2012 and came into effect in 2014. The advantages of using TK related to genetic resources are to be shared fairly and equally under Article 5(5). Article 12 acknowledges the importance of customary laws and community norms, whereas Article 7 underlines the consent and participation of the relevant communities. [26] Because they priorities community

[23] The Biological Diversity Act, 2002 (Act No. 18 of 2003).
[24] *Bayer Corporation v. Union of India*, 2014 SCC OnLine Bom 687.
[25] The Convention on Biological Diversity, 1992, arts. 8(j), 15.
[26] The Nagoya Protocol, 2010, arts. 5(5), 7, 12.

involvement in addition to governmental control when regulating access to related TK, these rules are important for India.

The TRIPS Agreement is the second strand. As of the now, it does not specifically require patent applications to reveal the sources of biological resources or related TK. The 2001 Doha

Ministerial Declaration instructed the TRIPS council to investigate the connection between TRIPS, the CBD, and TK protection. India and other developing nations have pushed for such a mandate. Nevertheless, this problem has not yet been fixed by a consensus-based amendment.[27]

The WIPO Treaty on IP, Genetic Resources, and Associated Traditional Knowledge,2024, is the third strand. When an invention is founded on genetic resources or related traditional Knowledge, it creates a patent disclosure obligation that includes disclosure of the nation of origin or source and, if relevant, the indigenous people or local community that provided the information. Information technologies that might help patent office's find pertinent in previous art are likewise encouraged under the Treaty.[28]

Rather than establishing property rights in TK itself, these documents mainly set requirements for consent, transparency, and benefit- sharing. Therefore, nationwide implementation has a major impact on their efficacy. The international framework supports Indias case for a coordinated system that combines defensive protection with significant community involvement and enhances the countries current patent and biodiversity laws.[29]

COMPARATIVE PERSPECTIVE

Many countries with rich indigenous history have made the preservation of TK a top priority. The maintenance and preservation of indigenous cultures traditional knowledge is seriously threatened in the new millennium due to the exponential rise of technology and the world’s fast globalization. Because it encompasses the community's culture, identity, and well-being, protecting this Tk is crucial.

In addition to providing guidelines, procedures, and suggestions for TK’s documentation,

[27] Agreement on Trade-Related Aspects of Intellectual Property Rights, arts. 27, 29, Apr. 15, 1994, 1869 U.N.T.S. 401.
[28] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, 2024, arts. 3–4.
[29] *Divya Pharmacy v. Union of India*, 2018 SCC OnLine Utt 722.

preservation, and equitable usage, WIPO has been at the forefront of providing international standards for its protection. Brazil, the Philippines, and Peru have established distinctive legal and regulatory solutions that balance the dual goals of guaranteeing fair benefit-sharing and preserving community rights, when TK plays a role in modern innovation. The directives of WIPO have some effect on these policies. A comparative analysis of different countries could teach India important insights on how to protect tribal knowledge under patent law.

1. Brazil

Brazil has steadfastly defended the rights of local communities and indigenous people to their traditional knowledge. Brazil is renowned for its enormous biological and cultural variety, which holds great promise for the advancement of biotechnology. In order to protect communities' rights to their cultural heritage, Law No. 13.123/2015[30] (Biodiversity Law) regulates access to genetic resources and associated TK. When using TK for research or commercial reasons, benefit-sharing and Prior Informed Consent (PIC) are mandated by law. Furthermore, Brazil's framework reflects the principle of national sovereignty over genetic heritage recognised under the CBD and est. Domestic mechanisms regulating access to genetic resources and associated traditional knowledge, including benefit- sharing obligations and protections for indigenous peoples and traditional communities.

2. Philippines

The Philippines is regarded as e regional leader in Asia for having enacted comprehensive laws pertaining to the rights of indigenous people. TK is collectively owned by indigenous cultural communities, according to the Indigenous people's Rights Act of 1997 (IPRA) The rights of indigenous people to their cultural and intellectual property, including traditional knowledge, are safeguarded by said law. Through the establishment of the National Council for Indigenous People, which is in charge of granting permits for access to indigenous people's lands, they will be able to control, develop, and safeguard their science, technologies, and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, essential medicinal plants, animals, and minerals, indigenous knowledge systems and practices, knowledge of the characteristics of

[30] *Ação Direta de Inconstitucionalidade (ADI) 6.890*, Supremo Tribunal Federal (Brazil), 2024.

fauna and flora, oral traditions, literature, designs, and visual performing arts.[31]

It provides protection beyond the purview of intellectual property regimes alone by guaranteeing the right to preserve, manage, and advance cultural customs and practices. Furthermore, TK and traditional cultural expressions are protected under standards established by the Intellectual Property Office of the Philippines (IPOPHL), which upholds the need for community consent before exploitation.[32] The Philippines is a prime example of inclusive law design because to its emphasis on cultural protection and administrative methods of IP registration.

3. Peru

For implementing one of the first sui generis regimes intended for TK, Peru has received praise. Peru unveiled a comprehensive legal framework in August 2002 with the goal of protecting indigenous people's collective knowledge. A unique system of protection for the collective knowledge of indigenous people about biological resources was established by Law No. 27811 of 2002. [33] The law creates contractual benefit-sharing structures, community consent procedures, and a national record of traditional knowledge. The Peruvian approach places special emphasis on the equitable involvement of indigenous populations in decision-making.

Peru permits TK's contribution to science while prohibits its appropriation.

TOWARDS A *SUI GENERIS* FRAMEWORK

The establishment of a specific Traditional Knowledge Protection Act is supported by the shortcomings of current methods. Such legislation should combine the Patents Act and the Biological Diversity Act, not replace them, and build upon the *sui generis* approach contemplated by Section 36(5) of the Biological Diversity Act.

In addition to defining and codifying traditional knowledge, the proposed law should acknowledge communities as stewards rather than absolute proprietors. Communities should be represented by BMCs, Gram Sabhas, or other approved customary institutions under collective, permanent, and unalienable custodianship. Joint custodianship and shared benefit

[31] *Cruz v. Secretary of Environment & Natural Resources*, G.R. No. 135385, 6 Dec. 2000 (Phil.).
[32] *CIR v. Secretary of Environment & Natural Resources*, G.R. No. 209033, 28 Sept. 2021 (Phil.).
[33] Law No. 27811 of July 24, 2002, Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (Peru).

procedures should be used when many communities exchange information.

Knowledge might be categorised as public, restricted, or confidential using a three-tier documentation system. Consent from the community and mutually agreed terms should be required for access to restricted or confidential knowledge. Benefits might include cash payments, royalties, technology transfer, education, or assistance with conservation. Additionally, the exception for codified TK should differentiate between commercial organisations that use the same knowledge at scale and traditional practitioners who use it for a living.[34]

To pursue injunctions, compensation, attribution, profit disclosure, and other suitable remedies, communities ought to have direct legal standing. The Patents Act should require the disclosure of the source of TK and evidence of community consent when an innovation is created using TK. In patent investigations, TKDL and authorized TK registries should be used efficiently.

A derivation test could differentiate between true innovation and traditional knowledge: genuinely new technical contributions should continue to be patentable subject to applicable disclosure and benefit-sharing requirements, while Section 3(p) should apply where the claimed technical effect is already known or easily ascertainable from TK.

Digital tools may help with documentation and proof, but community-approved processes must still be used to determine entitlement. Last but not least, successful implementation would require funding, training, legal assistance, and international cooperation. Such a system would boost community involvement without unnecessarily restricting legitimate research and innovation.[35]

CONCLUSION

TK holds a unique place in India because it is a source of income, biodiversity management, and prospective innovation in addition to intellectual and cultural heritage. Conventional IP law is therefore insufficient to solve it. Important defensive protections are offered by the Indian patent system. Inventions that are essentially traditional knowledge or that only replicate the recognized characteristics of historically known components are prohibited by Section 3(p) of

[34] *Divya Pharmacy v. Union of India* (2018).
[35] *D.C.M. Shriram Ltd. v. National Biodiversity Authority*, Appeal Nos. 1–3 of 2022 (National Green Tribunal, Southern Zone May 30, 2023)

the Patents Act, 1970. Additionally, traditional knowledge and local or indigenous knowledge are acknowledged as pertinent to patent opposition and revocation proceedings in Sections 25 and 64. By transforming recorded traditional medical knowledge into searchable prior art for patent assessment, the Traditional Knowledge Digital Library (TKDL) has greatly reinforced this framework. Its growth highlights the significance of efficient documentation in preventing the erroneous granting of patent rights, especially in light of the turmeric and neem patent conflicts. However, not all of the issues related to TK can be resolved by defensive protection alone

By controlling access to biological resources and related traditional knowledge and creating procedures for Access and Benefit Sharing, the Biological Diversity Act, 2002, along with its 2023 modifications and subsequent Rules, offers a supplementary framework. However, there are still significant issues with community involvement, prior informed consent, attribution, confidentiality, fair benefits, and the preservation of oral or unrecorded knowledge.

Therefore, a sui generis framework for Traditional Knowledge and more collaboration between the patent and biodiversity regimes are necessary for a holistic solution. Collective custodianship should be acknowledged, meaningful community involvement should be offered, oral and confidential information should be protected, prior informed consent and benefitsharing procedures should be strengthened, and suitable civil sanctions against misappropriation should be established. In order to prevent restrictions on legitimate research and innovation, it should also differentiate between genuinely new scientific contributions and old TK.

In addition to preventing misappropriation, traditional knowledge (TK) protection in India must acknowledge traditional groups as right holders and participants in the application and advancement of their knowledge. This means that in addition to protecting India's traditional knowledge from theft, the existing legal structure should acknowledge the TK's legal worth, guaranty its responsible use, and protect it for future generations.

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