Page: 2854-2878 *URL: www.lijdlr.com*

LAWFOYER INTERNATIONAL JOURNAL OF DOCTRINAL LEGAL RESEARCH

ISSN: 2583-7753

LawFoyer International Journal of Doctrinal Legal Research

[ISSN: 2583-7753]

Volume 4 | Issue 1

2026

DOI: https://doi.org/10.70183/lijdlr.2026.v04.127

PROTECTION OF TRADITIONAL KNOWLEDGE IN INDIA

Anjali Patel[1]

I. ABSTRACT

The traditional knowledge (TK), a set of medicinal formulations, agricultural practices, cultural expressions and ecological wisdom that has evolved in indigenous and local communities over centuries takes a controversial place in the modern intellectual property (IP) landscape. India, with one of the richest TK heritages in the world, especially in Ayurveda, Unani, Siddha, and Yoga has been in the forefront of the universality of TK protection. Bio-piracy, the systematic misappropriation of Indian traditional knowledge, where foreign organizations patent knowledge already existing in classical Indian literature, led to the establishment of the Traditional Knowledge Digital Library (TKDL), a searchable, multi-lingual, electronically structured searchable database, which was intended to serve as prior art in international patent courts. This paper evaluates critically the architecture, institutional structure, legal foundation, success and weaknesses of TKDL. It also examines the international legal tools applicable to TK protection such as the Convention on Biological Diversity (CBD), Nagoya Protocol, TRIPS Agreement, and WIPO Intergovernmental Committee (IGC) discussions, and outlines the most salient structural and political barriers to effective international TK protection. The approach to India is framed in terms of a comparative approach based on China, Brazil, South Africa, and Peru to locate the ways of reform. The paper concludes that although the TKDL is an essential defensive tool, India needs an integrated approach of a combination of robust sui generis positive protection law, reformed benefit-sharing systems, improved community management and a long-term effort to reform international law.

II. KEYWORDS

Traditional Knowledge, TKDL, Biopiracy, Sui Generis Protection, Nagoya Protocol.

[1] LL.M (IP), 2nd Semester, Student at Amity Law School, Amity University, Noida (India). Email: patelanjali9452@gmail.com

 (ISSN: 2583-7753)

III. INTRODUCTION

The interface between intellectual property law and traditional knowledge presents a complex and evolving challenge in contemporary legal discourse. Traditional knowledge, developed and preserved by indigenous and local communities over generations, encompasses medicinal practices, agricultural systems, and cultural expressions that are integral to community identity and survival. However, the modern intellectual property regime, which prioritizes novelty, individual ownership, and formal documentation, has proven inadequate in recognizing and protecting such collectively generated and orally transmitted knowledge systems. India, as a repository of diverse traditional knowledge systems such as Ayurveda, Unani, Siddha, and Yoga, has faced persistent instances of biopiracy, wherein foreign entities seek intellectual property protection over knowledge already existing within Indian traditions.

The turmeric and neem patent disputes exemplify the structural deficiencies in the global patent system, particularly the limited accessibility of traditional knowledge as prior art to patent examiners. In response, India established the Traditional Knowledge Digital Library as a defensive mechanism to prevent the misappropriation of its traditional knowledge in international patent regimes. This paper critically examines the role and effectiveness of the Traditional Knowledge Digital Library within India's broader legal and institutional framework for traditional knowledge protection. It further evaluates the interaction between domestic legal measures and international legal instruments such as the Convention on Biological Diversity, the Nagoya Protocol, and the TRIPS Agreement.

Through a comparative analysis of selected jurisdictions, the paper seeks to identify gaps in the existing framework and propose reforms aimed at developing a more comprehensive and equitable system for the protection of traditional knowledge.

A. Research Objectives

This paper seeks to critically evaluate the effectiveness of India's Traditional Knowledge Digital Library (TKDL) as a defensive mechanism against biopiracy within the international intellectual property framework. It aims to analyze the

adequacy of India's domestic legal framework for traditional knowledge protection, examine the interplay between national and international legal regimes, and identify structural gaps in existing mechanisms. The paper further seeks to derive comparative insights from selected jurisdictions such as China, Brazil, South Africa, and Peru in order to propose legal and policy reforms for strengthening traditional knowledge protection in India.

B. Research Questions

The study is guided by the following research questions:

1. To what extent does the Traditional Knowledge Digital Library effectively prevent biopiracy in international patent systems?
2. How adequate is India's domestic legal framework in providing both defensive and positive protection to traditional knowledge?
3. What are the limitations of existing international legal instruments such as the Convention on Biological Diversity, the Nagoya Protocol, and the TRIPS Agreement in addressing traditional knowledge misappropriation?
4. What lessons can India derive from comparative jurisdictions in designing a more robust and inclusive traditional knowledge protection regime?

C. Research Methodology

This paper adopts a doctrinal research methodology based on the analysis of primary and secondary legal sources. Primary sources include statutory provisions such as the Patents Act, 1970, the Biological Diversity Act, 2002, and relevant international instruments including the Convention on Biological Diversity, the Nagoya Protocol, and the TRIPS Agreement. Secondary sources include academic literature, policy reports, and case law relating to traditional knowledge and biopiracy. The study further employs a comparative analytical approach by examining traditional knowledge protection frameworks in jurisdictions such as China, Brazil, South Africa, and Peru. Additionally, the paper undertakes a qualitative analysis of select biopiracy case studies to evaluate the practical effectiveness of the TKDL and related legal mechanisms.

 (ISSN: 2583-7753)

IV. TRADITIONAL KNOWLEDGE: CONCEPT, CHARACTERISTICS, AND THE BIOPIRACY PROBLEM

The intersection of intellectual property law and traditional knowledge is one of the most controversial and ambiguous landscapes of modern legal studies. With the increasing pace of globalization, the issue of ownership of the knowledge that any indigenous and local community has gathered over the years has a deep legal, ethical, and geopolitical consequence in the context of exchange of biological resources and information across the borders. The traditional knowledge can be referred to as knowledge, innovations, and practices that have been created and maintained by the indigenous and local people through a long interaction with their environment, inherited across generations, and integrated within the cultural identity.[2] TK is shared, ancient, and almost entirely transmitted orally by practice and apprenticeship, unlike conventional IP, which assumes individual and novel and formally documented creation. This institutional imbalance is the root cause of the problem of TK protection: the current IP regime, which is structured to promote individual commercial innovation, does not acknowledge, safeguard, or appropriately reward the communities that create and maintain traditional knowledge. India holds a prestigious position as a store of traditional knowledge in the world. The ancient Indian subcontinent has had a rich legacy of traditional medical systems - Ayurveda, Unani, Siddha, Naturopathy, and Yoga, or thousands of years of empirical knowledge. Hundreds of thousands of formulas and treatment methods were documented in classical texts like the Charaka Samhita, Sushruta Samhita, Ashtangahridayam, and the Kitab al-Qanun fil-Tibb. But this heritage has been systematically exploited by biopiracy.[3]

This took on a new turn in 1995 with the United States Patent and Trademark Office (USPTO) patenting the ability of turmeric to heal wounds, properties that had been known in Ayurvedic texts since the beginning of time. In 1997, the Council of Scientific

[2] World Intellectual Property Organization (WIPO), Intellectual Property and Traditional Knowledge (WIPO 2015).
[3] Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge (Earthscan 2004).

and Industrial Research (CSIR) managed to contest and revoke this patent, but the incident revealed a systemic weakness: foreign patent examiners had no access to the great bulk of TK literature in India, most of which was written in Sanskrit, Tamil, Arabic and Persian. India responded by establishing the Traditional Knowledge Digital Library (TKDL) - an innovative institutionalized library that would subsequently block hundreds of biopiracy patents in international patent offices.[4] This paper is presented in the following way. Section II discusses the notion and nature of traditional knowledge. Part III is an analysis of the domestic legal protection of TK in India. Section IV will entail an in-depth analysis of the TKDL. Section V looks at international legal system and issues. Section VI reviews prominent cases of biopiracy and TKDL interventions. A comparative analysis is found in section VII. In Section VIII, conclusions and recommendations are provided.

A. Defining Traditional Knowledge

There is no universally accepted definition of traditional knowledge in the international law, and the lack of a definition has been an impediment in itself in international negotiations. According to World Intellectual Property Organization (WIPO), TK is knowledge, know-how, skills, and practices that are built, maintained, and transmitted across generations within a community and in part constitute its cultural or spiritual identity.[5] Article 8(j) of the Convention on Biological Diversity (1992) indirectly refers to the knowledge, innovations and practices of indigenous and local communities that represent traditional lifestyles.[6] Graham Dutfield and other academic experts like Madhavi Sunder differentiate between TK as a cognitive product and traditional practices as the resulting behaviours, whereas Madhavi Sunder stresses that TK is dynamic and contested and should not be reduced to pre-established characterizations that TK is fixed in time.

To use TK in the current paper, we shall conceptualize it as including traditional medical knowledge (herbal medicine, formulations, diagnostic techniques), agricultural and agro-ecological knowledge (seed varieties, soil management, pest

[4] CSIR/AYUSH, Traditional Knowledge Digital Library Annual Report 2019–20 (2020).
[5] WIPO, 'Traditional Knowledge' (WIPO Glossary, 2015).
[6] Convention on Biological Diversity 1992, art 8(j).

management), ecological and biodiversity knowledge (ecosystem management, species identification), artisanal and craft knowledge, and traditional cultural expressions such as performing arts and ritual practices.

B. Characteristics of Traditional Knowledge

There are several traits of direct legal relevance that allow differentiating TK and modern scientific knowledge. First, it is collectively owned and produced - invented, sustained and passed on not by isolated inventors but by communities over different generations, and it is not possible to single out a single patentable inventor. Second, it is intergenerationally disseminated, mostly by word of mouth through apprenticeship, oral storytelling and performing rituals, and is thus mostly invisible to patent examiners who seek written prior art[7]. Thirdly, it is entrenched in cultural and spiritual identity: Ayurvedic medicine, to take but an example, cannot exist outside of the philosophical system of the three doshas, Prakriti, and Pancha maha bhuta. Fourth, TK is dynamic and changing - communities keep changing and updating their knowledge - a fact that complicates the dichotomy between a so-called traditional and novel that the patent law implies. Fifth, TK tends to be diffuse, shared among many communities, in extensive geographical regions, which makes it difficult to attribute rights to individual communities or nations.

C. The Value of Traditional Knowledge

TK possesses scientific, economic, cultural and ecological values of the utmost order. Modern pharmaceutical drugs, in turn, are based on or inspired by traditional medicine research, with around 25 per cent of modern pharmaceutical drugs being based on or inspired by plant compounds. Examples are quinine (derived by Peruvian bark used by the peoples of the Amazon to treat malaria), morphine (opium poppy), and artemisinin (Artemisia annua of traditional Chinese medicine). The pharmaceutical research in India has focused on the antimicrobial property of neem, the anti-inflammatory property of turmeric, the adaptogenic property of Ashwagandha (With an iasomnifera), and the anti-diabetic property of Bitter Gourd.

[7] Posey and Dutfield, Beyond Intellectual Property (IDRC 1996).

The global market of herbal medicine has been estimated to be USD 83 billion in 2018 and is expected to go to USD 347 billion in 2030, economically. Ayurvedic medicine alone had a market of about INR 30,000 crore (USD 4 billion) in India. However, the communities which produce TK hardly receive these commercial advantages, which demonstrates the core equity aspect of the biopiracy issue.[8]

D. Biopiracy and the Public Domain Problem

Bio piracy is a term used by Canadian activist Pat Roy Mooney in the 1990s to describe the process of commercial entities obtaining IP rights over traditional knowledge and genetic resources of developing countries without payment to the source communities. The two attributes of the international IP system that enable biopiracy include globalization of the patent system under TRIPS which increased the range of patentable subject matter and the restricted prior art bases available to patent examiners in foreign offices which omits most of the TK literature in non-European languages.[9] One of the compounding paradoxes is the public domain problem. Since TK is old, it does not qualify to be patented as it fails to satisfy the novelty requirement, which is that a patent must cover something that is new to the world; in this case, TK falls under the domain of the common person and is technically free to use. However, source communities do not see their heritage as something free, they see it as their own and it is governed by customary law. The handling of TK as a public domain, through the IP framework, is equally dehumanizing of the communities in the sense that they are deprived of any right or economic profit of the commercialization of their heritage.

V. INDIA'S DOMESTIC LEGAL FRAMEWORK FOR TK PROTECTION

A. Patent Law

The Patents Act 1970 of India as it is extensively revised in 2002 and 2005 includes a number of clauses that are of paramount importance to the protection of TK. Section

[8] UNCTAD, Protecting and Promoting Traditional Knowledge (2004).
[9] Pat Roy Mooney, 'The Parts of Life' (1990).

3(p) as inserted by the 2002 amendment specifically provides that no invention that is essentially traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components shall be patented.[10] This is a strategic legislative decision to avoid monopolization of TK. Section 3(d), one of the most controversial clauses in international trade law, prohibits patents on new forms of known substances unless they demonstrate enhanced therapeutic efficacy, thereby limiting the grant of patents on modified traditional knowledge-based preparations.

The scope of this provision was authoritatively interpreted by the Supreme Court of India in Novartis AG v. Union of India, (2013) 6 SCC 1, where the Court held that mere improvements in physico-chemical properties are insufficient and that enhanced therapeutic efficacy must be strictly demonstrated. This interpretation has significantly strengthened India's safeguards against evergreening and the patenting of incremental innovations derived from traditional knowledge, while also contributing to the global discourse on TRIPS flexibilities for developing countries. Section 25(1)(j) and 25(2)(j) permit both pre-grant and post-grant opposition of patents over the basis that the proposed invention is foreseen in terms of knowledge accessible within any local or native grouping, either orally or in writing.

This clarification of oral TK as a valid prior art is a substantial deviation in most jurisdictions which require written publicity and demonstrates that India is serious in its goals to safeguard TK in its original transmitted state. The TKDL is a practical implementation of these provisions, transforming documented oral and classical TK into electronically searchable prior art available to foreign patent examiners.

B. The Biological Diversity Act, 2002

Access and benefit-sharing (ABS) framework of the CBD is incorporated into the Biological Diversity Act (BDA), 2002, which establishes a three-tier institutional framework of the National Biodiversity Authority (NBA) on the national level, State Biodiversity Boards (SBBs) on the state level, and Biodiversity Management

[10] Patents Act 1970 (India), s 3(p).

Committees (BMCs) on the local BDA stipulates in Section 6 that any application of any IP right within or without India based on biological resources originating in India must be preceded by permission of the NBA a mandatory disclosure and consent system that aims to interdict biopiracy patents as soon as they are filed.[11]

The BDA also requires the establishment of the People Biodiversity Registers at local level, i.e. community records on the biological resources and related TK which are not only used as documentation resource but also used as an evidentiary in patent opposition proceedings.

The BDA framework, however, has been subject to criticism on a number of fronts: unequal application among states, the lack of a sufficient benefit sharing fund, insufficient coverage of commercial use outside the patent system, and the lack of positive IP rights to TK-holding communities.

C. Geographical Indications, Plant Varieties, and Sui Generis Frameworks

The Geographical Indications of Goods (Registration and Protection) Act, 1999 provides a good protection of TK-related artisanal and agricultural products - Darjeeling Tea, Kanchipuram Silk, and Basmati Rice are some of the registered GI in India.[12] Nevertheless, GI protection does not endanger the use of TK-based techniques in other areas, but in fact secures the geographical name itself, without considering the underlying TK. The Protection of Plant Varieties and Farmers Rights Act, 2001 (PPVFRA), which is widely recognized as one of the most farmer-friendly laws worldwide on plant varieties protection, recognizes the rights of the farmers to save, sow, and sell farm produce of the covered varieties and to share in the benefits through a National Gene Fund.[13]

National Innovation Foundation documents and patents grassroots TK-based innovations, which offers an aspect of positive protection not available in the TKDL model. There is still no enacted comprehensive sui generis TK protection legislation in India, despite the extensive advocacy of scholars and civil society. A properly

[11] Biological Diversity Act 2002 (India).
[12] Geographical Indications of Goods Act 1999 (India).
[13] Protection of Plant Varieties and Farmers' Rights Act 2001.

developed sui generis system would create community owned IP over registered TK, a multilevel access register, compulsory prior informed consent to commercial use and a benefit sharing fund - covering the positive protection gap that the TKDL cannot fulfill.

VI. THE TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL): ARCHITECTURE, ACHIEVEMENTS, AND LIMITATIONS

A. Genesis and Institutional Framework

TKDL was formed as a joint venture between CSIR and the Department of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) and was started in the year 2001.[14] The underlying premise was simple and deep: biopiracy patents were actually being issued not due to the novelty of the knowledge being claimed, but because patent examiners in Washington, Munich and Tokyo could not access the classical TK literature in India. India would be able to convert its traditional heritage into globally available prior art by digitizing, translating and organizing this knowledge into a multilingual searchable database.

The project was structured as a team of specialized interdisciplinary team of scientists, Ayurvedic doctors, Unani hakims, Siddha, yoga, patent lawyers, IT experts and linguists. It was an interdisciplinary composition: not only had to be translated and transcribed the classical texts in Sanskrit, Arabic, Persian, and Tamil, but a specialized system of classification was necessary, called the Traditional Knowledge Resource Classification (TKRC), to match the International Patent Classification (IPC) system of most patent offices around the world.

B. Architecture and Content

The TKDL presently contains details of over 5.2 lakh (approximately 520,000) medicinal formulations and practices, as reported in recent official data, with its foundational content historically derived from 148 classical texts across the four traditional knowledge systems:

[14] CSIR/AYUSH (n 4).

1. **Ayurveda:** Founded upon textual basis, such as the Charaka Samhita, Sushruta Samhita, Ashtangahridayam and Sharangdhara Samhita, which deal with formulations, ingredients, modes of preparation, medical uses, as well as dosages.
2. **Unani:** This is based on classical works of Greco-Arabic like the Kitab al-Qanun fil-Tibb and Makhzan al-Adwiya in Arabic and Persian.
3. **Siddha:** According to the traditional texts of South India of the Tamil-language, such as Agastiyar Paripuranam.
4. **Yoga:** The recording of traditional yoga postures, pranayama methods, and practices of the Yoga Sutras of Patanjali, Hatha Yoga Pradipika and the Gheranda Samhita.
5. **The most notable innovation is the TKRC:** Developed in conjunction with WIPO and the European Patent Office, it enabled the incorporation of approximately 200 sub-groups under A61K 36/00 of the International Patent Classification to better accommodate traditional knowledge-related formulations. The broader TKRC system classifies traditional knowledge into several thousand sub-groups across multiple domains. A tremendous institutional success of the incorporation of traditional knowledge into the global patent classification framework, the TKRC has been integrated into the process of IPC revision.[15]

The TKDL comes in five languages, English, German, French, Japanese and Spanish, the languages of working of the major patent offices and it specifically targets the language barrier that has long served to shield biopiracy applications against Indian prior art.

C. Access Framework

Instead of making the database publicly available, and thus potentially enabling commercial misuse, the TKDL has a bilateral agreement with patent offices on controlled-access basis. Contracts are signed with EPO, USPTO, JPO, UK IPO, German Patent Office and more recently with Brazilian, Canadian, and South Korean patent

[15] WIPO, IPC Classification Documents.

offices. According to such agreements: TKDL data cannot be used outside the examination of patents; it cannot be referred to as non-publishable prior art (can be mentioned by examiners in rejection without revealing the text behind it to the applicants); nor can it be utilized in research and development.[16]

The non-publication clause has received criticism. The opponents believe that it undermines transparency and can lead inadvertently to biopiracy outside of the patent system. The Government of India insists on such a balance in order to avoid the transformation of TKDL into a commercial exploitation resource.

D. Performance and Achievements

More than 375 biopiracy-related patent applications have been revoked, rejected, amended, withdrawn, or abandoned worldwide with the intervention of the Traditional Knowledge Digital Library across multiple international patent offices, as reported in recent official data published by the Council of Scientific and Industrial Research and the Press Information Bureau. A significant percentage of traditional medicine applications considered by the EPO based on TKDL information was rejected, withdrawn or significantly limited. The USPTO also claimed instant effect after the agreement of access. The deterrent effect -applications that are never submitted due to the advice of patent attorneys to consult TKDL beforehand may be equally meaningful but is by nature not measurable.

In the particular instance of yoga, the TKDL Yoga module, which records about 900 yoga postures in classical texts, was established in 2010 in response to the increasing number of yoga-related patent applications filed in the United States, particularly highlighted by reports in 2007 that identified over 100 such patents. This development prompted governmental and parliamentary concern, leading to systematic documentation efforts. Subsequently, in Bikram's Yoga College of India, L.P. v. Evolation Yoga, LLC, 803 F.3d 1032 (9th Cir. 2015), the United States Court of Appeals for the Ninth Circuit clarified that yoga sequences are not protectable under copyright law. Although yoga postures do not fall within the conventional framework of patent

[16] European Patent Office, TKDL Access Agreement Reports.

prior art, the TKDL Yoga module serves as an important international repository documenting the traditional origins of yoga practices.

E. Shortcomings of the TKDL

The shortcomings of the TKDL are as significant to know as its successes. To begin with, it will only offer defensive protection: it will block the issuance of biopiracy patents but not confer any positive IP rights on the TK-holding communities, will not create a benefit-sharing system, and will not eliminate commercial exploitation of TK outside the patent system. The TKDL could enable a pharmaceutical firm to gain an insight into the potential Ayurvedic formulations and come up with commercial products that are built around these potentials, and no legal action can be taken against it under the existing framework.

Second, the TKDL contains only written classical works of codified TK systems. It is lost entirely the oral, living, and uncodified TK possessed by tribal and indigenous communities, which could have commercial value and be misused as much as it might be valuable. Similarly excluded are agricultural TK, ecological knowledge and artisanal knowledge.[17] Third, the controlled-access system restricts the publicity and community involvement in the governance. Communities whose TK is recorded played minimal roles in the creation of the TKDL and do not directly benefit by the interventions of TKDL. Fourth, the TKDL documents TK as found in classical texts - a historical record - with more modern adaptations and inventions by traditional practitioners not secured. Fifth, the protective scope is restricted in its scope of jurisdiction to the patent offices to which an access agreement has been made.

VII. INTERNATIONAL LAW FRAMEWORK AND PROBLEMS

A. The Convention on Biological Diversity (1992)

It is based on three pillars that are conservation of biodiversity, sustainable use, and fair and equitable benefit-sharing of the use of genetic resources, which is the basis of the CBD, which was adopted in June 1992 and now has 196 parties. Article 8(j) obligates parties to respect, preserve and maintain TK of indigenous and local

[17] R Kumar, 'TKDL and International IP' (2019) 24 JIPR 189.

communities relative to biodiversity conservation, encourage its broader use with the approval and participation of holders and encourage equitable sharing of benefits.[18] Although Article 8(j) marks the first acknowledgment of TK in the international environmental law, it has a limitation in the wording of being subject to national legislation and is not binding.

B. The Nagoya Protocol (2010)

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising out of their use, adopted in 2010 and entering into force in 2014, having 142 parties as of recent data, was meant to implement the Access and Benefit-Sharing framework of the Convention on Biological Diversity. Article 7 obliges parties to make sure that TK that is related to genetic resources owned by indigenous and local communities is not accessed without their prior informed consent (PIC) and on mutually agreed conditions.[19] Article 12 asks parties to take into account customary laws and community procedures when controlling access to TK.

With these developments, the limitations of the Protocol are immense. It merely discusses TK in relation to genetic resources, not much of the agricultural, artisanal, and non-resource-related TK. It does not generate any beneficial IP rights. Its compliance provisions are comparatively poor, as they rely on national legislation, which differs greatly in quality and rigor. It does not deal with legacy biopiracy - misappropriation that has taken place prior to it taking effect. Most importantly is the fact that the connection between the Protocol and the TRIPS Agreement has not been established and as a result patent-based biopiracy is not under its jurisdiction.

C. The TRIPS Agreement and Its Built-in Tensions

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1994, establishes minimum standards for the protection of intellectual property, including patents, across member states of the World Trade Organization. It requires that patents be granted for inventions that are novel, involve an inventive step, and are capable of industrial application. However, TRIPS do not explicitly

[18] Convention on Biological Diversity 1992.
[19] Nagoya Protocol 2010.

address traditional knowledge. It neither mandates the exclusion of traditional knowledge-based inventions from patentability nor requires disclosure of the origin of such knowledge in patent applications. As a result, traditional knowledge is often treated as part of the public domain within the international patent system, permitting its use without recognition or compensation to the originating communities.

This divergence has generated a persistent normative tension between the TRIPS Agreement and the Convention on Biological Diversity. While TRIPS facilitates the grant of patent rights, the Convention on Biological Diversity emphasizes prior informed consent and equitable benefit-sharing in relation to access to genetic resources and associated traditional knowledge. Developing countries, including India and Brazil, have consistently advocated for the incorporation of mandatory disclosure of origin requirements within the TRIPS framework. In contrast, several developed countries, including the United States, the European Union, Japan, and Canada, have opposed such amendments on the ground that they may introduce legal uncertainty into the patent system. This disagreement has remained unresolved within the TRIPS Council for over two decades.

D. The WIPO IGC Negotiations

In response to these challenges, the World Intellectual Property Organization established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in 2000. The Committee serves as a forum for negotiations on the international legal protection of traditional knowledge. Since 2009, discussions have progressed toward the development of draft treaty provisions, with countries such as India advocating for mandatory disclosure requirements, recognition of community rights, and equitable benefit-sharing mechanisms.

While for more than two decades no binding treaty emerged due to persistent disagreements over the nature, scope, and beneficiaries of protection, a significant breakthrough occurred with the adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (24 May 2024). This treaty constitutes the first binding international instrument addressing the interface between

intellectual property and traditional knowledge in the patent context. Notably, it introduces a mandatory disclosure requirement under which patent applicants must identify the country of origin of genetic resources and, where applicable, the indigenous or local communities providing associated traditional knowledge. However, the treaty remains limited in scope as it focuses primarily on disclosure obligations rather than creating substantive or positive rights for traditional knowledge holders, thereby reflecting a narrower outcome than that advocated by several developing countries, including India.

E. UNDRIP and the Rise of Human Rights for TK

When it comes to wrapping TK protection in human rights language, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) leads the way. Adopted in 2007, it puts the power squarely in indigenous peoples' hands, saying they have the right to preserve, control, and develop their cultural heritage and TK including intellectual property rights. UNDRIP also tells countries they must consult with indigenous groups before passing any new laws that touch on these rights.[20] It isn't legally binding, but plenty of courts and international talks have started using UNDRIP to back up TK claims. It gives communities a much broader platform—one that reaches beyond the usual IP and trade debates.

F. The Big Structural Challenges

There's no easy fix for TK protection, and the roadblocks aren't going away. First up: the "public domain paradox." Current law lets anyone use TK while shutting out the communities that created it from owning any rights. Then, there's the classic North-South divide the interests of wealthy countries often clash sharply with TK holders, and these wealthier countries have more negotiating power to resist binding rules. Defining what "traditional knowledge" even means remains unsettled, which makes it tough to agree on who should benefit from new laws. Enforcement is another joke; even existing agreements like the Nagoya Protocol don't get enforced, and there's no international court with power over TK misappropriation. And a new danger is

[20] UN Declaration on Rights of Indigenous Peoples 2007.

emerging: digital technology. AI and machine learning now scan and learn from digitized TK, fueling fresh patents and innovations while sidestepping any requirement to share benefits with original TK holders.

VIII. BIOPIRACY CASE STUDIES AND TKDL INTERVENTIONS

A. The Turmeric Case (1995–1997)

Here's one for the history books. In 1995, the US Patent and Trademark Office gave a patent to the University of Mississippi Medical Centre for using turmeric to heal wounds as if it were a groundbreaking new idea. CSIR of India stepped in, digging up hard evidence from Ayurvedic texts, a 1953 medical article, and even the Rigveda, all showing turmeric's healing powers had been known for centuries. Faced with this mountain of proof, the US cancelled the patent in 1997.[21] This was the first time anyone successfully scrapped a biopiracy patent using TK as prior art. But it also showed just how much time and energy it takes to fight even one bad patent after it's been granted which pushed India to create a large, proactive database for defending its TK.

B. The Neem Case (1994–2000)

Something similar occurred with neem. The US Department of Agriculture and W.R. Grace obtained a European patent for a process using neem oil to control plant fungus. The patent was formally challenged before the European Patent Office by Dr. Vandana Shiva's Research Foundation for Science, Technology and Ecology, the International Federation of Organic Agriculture Movements, and MEP Magda Aelvoet. The opposition demonstrated that Indian farmers had long utilized neem's antifungal properties as part of traditional agricultural practices. Following extensive proceedings, the European Patent Office concluded that the claimed invention lacked novelty and revoked the patent in 2000.

C. The Basmati Case (1997–2002)

In 1997, RiceTec Inc. in Texas grabbed a US patent for "basmati rice lines and grains," plus the right to sell its rice as "basmati" in the States. India wasn't having it. They challenged RiceTec on several fronts, through the US Patent Office, US trade talks, and

[21] In re Das and Cohly (1997) USPTO.

even the WTO. Pressured by India, RiceTec had to drop the worst of its patent claims.[22] It was a partial win; RiceTec's patent wasn't entirely gone, but the case highlighted the limits of relying on prior art especially for truly new varieties bred from traditional stock. But this fight did push India to secure Geographical Indication (GI) status for Basmati rice in the EU, showing that GI and patent law can work together to protect TK.

D. After TKDL: Stopping Biopiracy Before It Starts

In 2009 and 2010, once TKDL set up its access agreements, its effect was dramatic. Patent applications on Ashwagandha (known in Ayurveda as a powerful adaptogen) kept getting rejected at the US and European patent offices because of prior art from TKDL. The same thing happened with Triphala an ancient Ayurvedic herbal combo used for digestion and immunity and with Jamun, traditionally used to treat diabetes.[23] Applications were denied because TKDL records proved prior use.

But that's not all. The presence of the TKDL database is now so well-known that lawyers routinely advise applicants for nutraceutical and pharmaceutical patents to check it first. Many don't even bother applying if their inventions overlap with documented TK. It's a real deterrent and it stops biopiracy in its tracks before it becomes a legal headache.

IX. COMPARATIVE ANALYSIS: LESSONS FOR INDIA

1. **China:** China has adopted an active and multifaceted approach to the protection of traditional knowledge. It has developed a Traditional Chinese Medicine Patents Database analogous to India's TKDL, while also enacting the Intangible Cultural Heritage Law in 2011 and encouraging practitioners to seek protection through patents and trademarks. Two key lessons emerge for India: first, the scalability and effectiveness of database-driven defensive protection

[22] RiceTec Inc v India (2001) USPTO.

[23] CSIR/AYUSH, *TKDL Annual Report 2019–20* (TKDL Unit, New Delhi 2020); Biswas S, 'Traditional Knowledge and Intellectual Property Rights: The TKDL as a Model for Protection' (2016) 21 Journal of Intellectual Property Rights 123; Kumar R, 'TKDL and International Intellectual Property: An Assessment of India's Defensive Strategy Against Biopiracy' (2019) 24 Journal of Intellectual Property Rights 189.

mechanisms; and second, the value of integrating cultural heritage legislation with intellectual property frameworks to provide broader recognition and protection for traditional knowledge.

2. **Brazil:** Brazil's Biodiversity Law of 2015 adopts a broader approach by regulating diverse forms of commercial utilization of genetic resources and traditional knowledge, thereby addressing gaps beyond the patent system. Its notification and benefit-sharing mechanism, administered by the Genetic Heritage Management Council, provides a comparatively flexible framework. Additionally, Brazil's constitutional recognition of indigenous cultural and land rights strengthens the protection of traditional knowledge within a human rights framework. However, implementation challenges, including administrative delays and limited benefit-sharing funds, highlight the importance of institutional capacity in ensuring the effectiveness of legal frameworks.
3. **South Africa:** South Africa has pursued a distinct approach through instruments such as the Traditional Health Practitioners Act, 2007, and the proposed Indigenous Knowledge Protection framework, which emphasize community ownership, national databases, and structured benefit-sharing. Although implementation remains incomplete, these measures provide a valuable model. The 2019 rooibos tea agreement, concluded between producers, the government, and the Khoisan community, represents a notable example of a functional benefit-sharing arrangement that ensures community participation in the commercialization of traditional knowledge.
4. **Peru:** Peru provides a comprehensive legislative model through Law No. 27811, which establishes a structured system for the protection of traditional knowledge. Its three-tier registration mechanism, consisting of private, local, and public registers, enables communities to control access to their knowledge while creating community-based intellectual property rights. The framework incorporates mandatory prior informed consent and a national benefit-sharing fund. Additionally, Law No. 28216 established the National Commission against Biopiracy, which actively monitors global patent systems and

challenges instances of misappropriation. This integrated approach offers a valuable model for future policy development in India.

5. **Synthesis of Comparative Lessons:** A synthesis of these comparative approaches reveals several common principles relevant to India. First, while database mechanisms such as the TKDL are effective for defensive protection, they are insufficient in isolation. Second, meaningful participation of traditional knowledge-holding communities and equitable benefit-sharing are essential for legitimacy and sustainability. Third, comprehensive protection requires integration across intellectual property, biodiversity, and cultural heritage frameworks. Finally, the effectiveness of legal provisions depends on adequate institutional capacity, financial resources, and enforcement mechanisms.

X. CONCLUSION AND RECOMMENDATIONS

A. Synthesis of Findings

India's earned its place as a leader in protecting traditional knowledge, thanks mainly to the TKDL. This database stopped hundreds of biopiracy patents cold and probably deterred many more. TKDL's technical advancements, multilingual interface, robust access controls these aren't just local wins; they influence global best practices. big gaps are staring India in the face. The TKDL only plays defence: there are no positive rights created no benefit-sharing from commercial exploitation, and oral or unwritten TK gets left behind.[24] Domestically, laws are advanced in patches but remain scattered and unevenly applied; they mostly aim to stop theft rather than promote fair use.

On the global stage, frameworks such as the Convention on Biological Diversity, the Nagoya Protocol, and the TRIPS Agreement have historically been constrained by North-South divisions, definitional ambiguities, and weak enforcement mechanisms. Although the adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge in 2024 marks a significant normative development, particularly through its disclosure of origin requirement, it

[24] Mashelkar R A, Intellectual Property Rights: Why India Needs to Be Proactive (2001).

does not fully resolve these structural challenges, as it stops short of establishing comprehensive substantive rights or robust benefit-sharing mechanisms for traditional knowledge holders.

B. Recommendations

Here's what should happen next:

1. **Pass robust TK legislation, inspired by Peru's model:** India needs a full-fledged law with three tiers of national TK registration (private, restricted, and public), where communities hold the rights over their own knowledge. There must be clear benefit-sharing from any commercial revenue and consent must always be sought. Cover every type of TK medical, agricultural, ecological, artisanal and protect both written and oral forms.
2. **Boost Biodiversity Act (BDA) implementation:** State Boards and Committees need more funding and authority. Make Section 6 disclosure requirements non-negotiable, with patent cancellation for any slip-ups. Transparency in benefit-sharing and ramped-up funds are non-negotiable.
3. **Fix the Patents Act:** Examiners must check the TKDL when reviewing patent applications. Strengthen "disclosure of origin" - if you hide or fudge origin, you lose your patent. Tighten Section 3 so that it blocks "innovations" lifted straight from existing TK, unless there's a genuine new inventive step.
4. **Reform the TKDL:** Cover oral, living, and tribal knowledge bring in People's Biodiversity Registers. Overhaul governance so that community voices are officially involved. If communities' TK is used to block biopiracy, make sure they receive proper compensation.
5. **Set up a National Biopiracy Monitoring Centre:** Using Peru's NCAB as a blueprint, create a central body within CSIR or NBA to scan global patent databases, file oppositions where needed, and release public annual reports.
6. **Push for a binding international TK treaty:** Keep championing a strong treaty at WIPO IGC one that mandates origin disclosure, positive protection, free, prior, and informed consent (PIC), fair benefit-sharing, and

teeth for enforcement. Keep up the alliances with the African Group, Like-Minded nations, and biodiversity giants.

7. **Advocate for a TRIPS amendment:** Keep up the pressure at the WTO force mandatory origin disclosure for patents and use linkage with other trade issues to strengthen India's hand.
8. **Close bilateral TK agreements:** While the world haggles over a global treaty, strike deals with key trade partners mutual recognition of TK, recognition of PIC, sharing of benefits, and real cooperation on enforcement**.**

C. Concluding Observations

Protecting India's traditional knowledge isn't just a legal battle. It's a moral responsibility and it's about recognizing the worth and dignity of India's ancient civilizations. The TKDL proves you can design practical solutions against misappropriation. The next step is clear: build on this foundation by expanding the scope of the TKDL, enacting comprehensive sui generis protection legislation, and ensuring meaningful participation of traditional knowledge holders in governance frameworks. At the international level, India must engage proactively with the implementation of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge while continuing to advocate for broader reforms that move beyond disclosure obligations toward substantive rights, equitable benefit-sharing, and stronger enforcement mechanisms.[25]

The civilizations behind the Charaka Samhita, the Kitab al-Qanun, the Yoga Sutras who spent centuries building up some of the world's most extraordinary medical, agricultural, and ecological wisdom deserve nothing less.

XI. REFERENCES

A. Primary Sources

1. Legislation (India)

- Patents Act, 1970 (No. 39 of 1970), as amended by the Patents (Amendment) Acts of 1999, 2002, and 2005.

[25] UNCTAD (n 13).

- Biological Diversity Act, 2002 (No. 18 of 2003) and Biological Diversity Rules, 2004.
- Geographical Indications of Goods (Registration and Protection) Act, 1999 (No. 48 of 1999).
- Protection of Plant Varieties and Farmers' Rights Act, 2001 (No. 53 of 2001).

2. International Instruments

- Convention on Biological Diversity, 1760 UNTS 79 (opened for signature 5 June 1992, entered into force 29 December 1993).
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, UN Doc UNEP/CBD/COP/DEC/X/1 (adopted 29 October 2010, entered into force 12 October 2014).
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299 (15 April 1994).
- International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (adopted 3 November 2001, entered into force 29 June 2004).
- United Nations Declaration on the Rights of Indigenous Peoples, UNGA Res 61/295 (13 September 2007).
- WIPO IGC, Draft Articles on Traditional Knowledge (WIPO/GRTKF/IC/40/4, 2020).

3. Cases

- In re Das and Cohly (Turmeric Patent Case), US Patent No. 5,401,504, USPTO Re-examination Proceeding (1997).
- US Department of Agriculture and W.R. Grace & Co. (Patentees) v. Vandana Shiva and others (Opponents), EPO Opposition Division Decision (10 May 2000), EP 0436257 B1; EPO Technical Board of Appeal, Decision (8 March 2005).

- RiceTec Inc. v. India, USPTO Re-examination of US Patent No. 5,663,484 (2001) (Basmati case).
- Bikram's Yoga College of India, L.P. v. Evolation Yoga, LLC, 803 F.3d 1032 (9th Cir. 2015).
- Novartis AG v. Union of India and others, (2013) 6 SCC 1.

B. Secondary Sources

1. Books and Monographs

- Blakeney M, The Protection of Traditional Knowledge Under Intellectual Property Law (Cambridge University Press, Cambridge 2017).
- Dutfield G, Intellectual Property, Biogenetic Resources and Traditional Knowledge (Earthscan, London 2004).
- Gupta V K, Traditional Knowledge Digital Library: From Vision to Reality (CSIR, New Delhi 2011).
- Mashelkar R A, Intellectual Property Rights: Why India Needs to Be Proactive (CSIR, New Delhi 2001).
- Mgbeoji I, Global Biopiracy: Patents, Plants, and Indigenous Knowledge (UBC Press, Vancouver 2006).
- Posey D A and Dutfield G, Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities (IDRC, Ottawa 1996).
- Shiva V, Biopiracy: The Plunder of Nature and Knowledge (South End Press, Boston 1997).
- WIPO, Intellectual Property and Traditional Knowledge (Booklet No. 2) (WIPO, Geneva 2015).

2. Journal Articles

- Biswas S, 'Traditional Knowledge and Intellectual Property Rights: The TKDL as a Model for Protection' (2016) 21 Journal of Intellectual Property Rights 123.

- Dutfield G, 'TRIPS-Related Aspects of Traditional Knowledge' (2001) 33 Case Western Reserve Journal of International Law 233.
- Gopalakrishnan N S and Nair T G, 'Addressing the Failures in the Traditional Knowledge Protection Regime through TKDL' (2012) 17 Journal of Intellectual Property Rights 398.
- Gupta V K, 'Traditional Knowledge Digital Library (TKDL): A Protective Mechanism for India's Traditional Knowledge' (2011) 3 Journal of Intellectual Property Rights 292.
- Helfer L R, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 Yale Journal of International Law 1.
- Kumar R, 'TKDL and International Intellectual Property: An Assessment of India's Defensive Strategy Against Biopiracy' (2019) 24 Journal of Intellectual Property Rights 189.
- Tsioumani E, 'The Nagoya Protocol on Access and Benefit-Sharing: Prospects for Legal Implementation' (2010) 2 Yearbook of International Environmental Law 1.
- Verma S K, 'Protecting Traditional Knowledge: Is a Sui Generis System an Answer?' (2004) 7 Journal of World Intellectual Property 765.

C. Reports and Official Documents

1. CSIR/AYUSH, TKDL Annual Report 2019-20 (TKDL Unit, New Delhi 2020).
2. Government of India, National Biodiversity Authority, Annual Report 2020-21 (NBA, Chennai 2021).
3. UNCTAD, Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions (UN, Geneva 2004).
4. WIPO, 'Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Forty-Third Session' (WIPO/GRTKF/IC/43/10, 2022).
5. TKDL official website: www.tkdl.res.in.