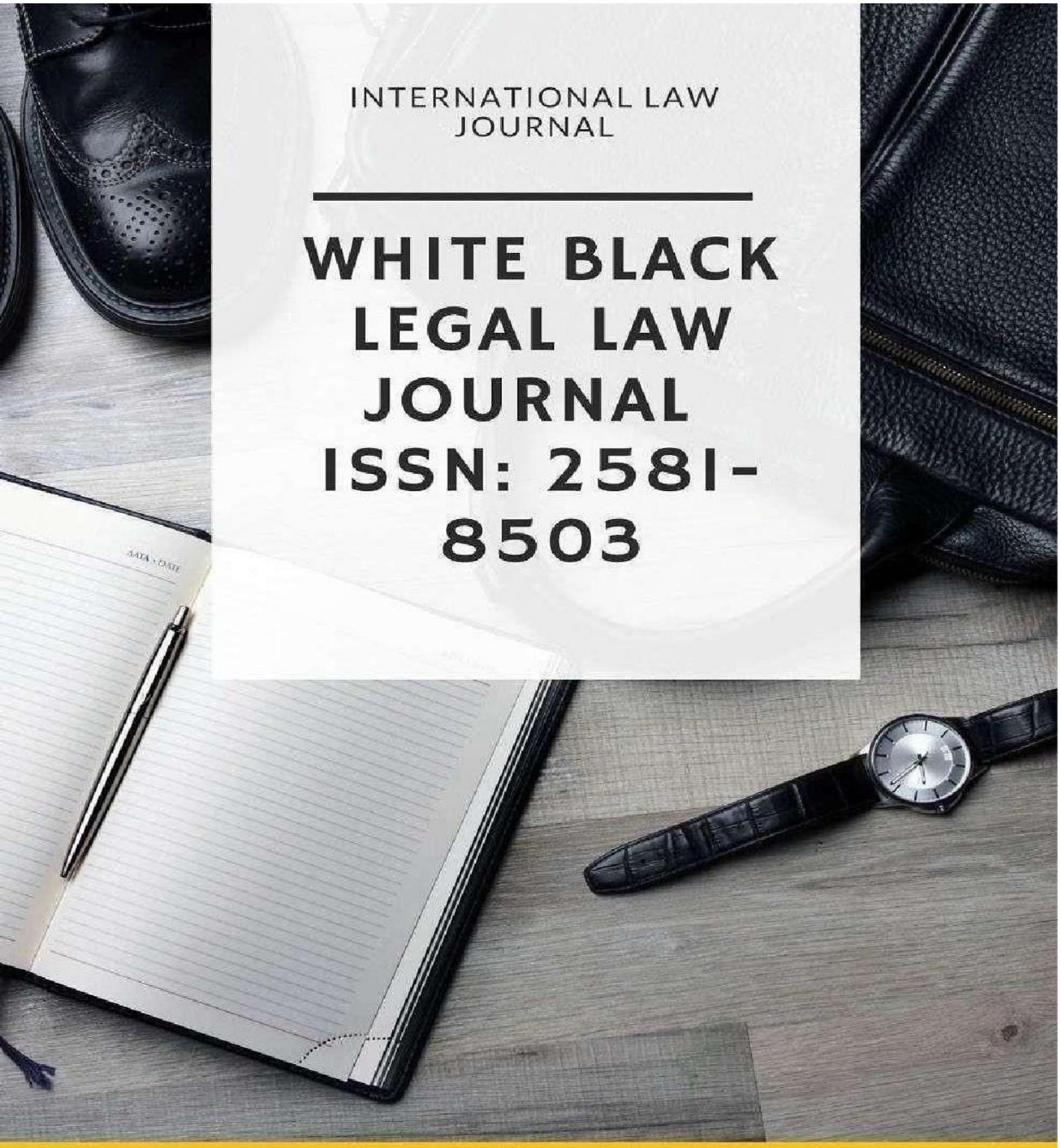

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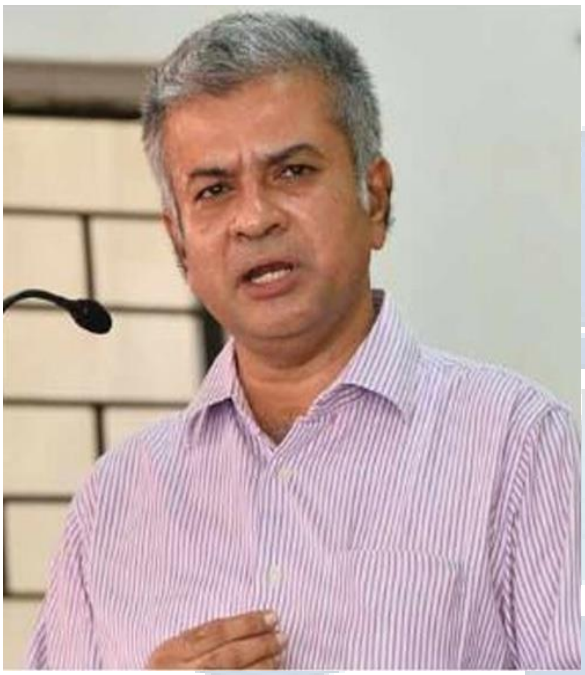

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With this thought, we hereby present to you

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# PROTECTION OF TRADITIONAL KNOWLEDGE FROM BIOPIRACY: LEGAL FRAMEWORK AND ITS EFFECTIVENESS

AUTHORED BY - MAHITHA CHAKRAVARTHI

## I. Abstract

In India, it is typical in one's home to use turmeric on cuts and wounds since it has healing properties as an antiseptic. One of many practices of healing, this is learned from our elders and can be termed as traditional knowledge. It was therefore quite shocking when an application for a patent was submitted by some company in another nation for the same. This is typical instance of bio-piracy regarding traditional knowledge. This paper examines the community aspect of traditional knowledge and how this in itself presents a hurdle in securing and protecting it from biopiracy. The paper looks into particular instances of biopiracy which include that of neem, turmeric and basmati rice. It then takes cognizance of the current legal regime in place that seeks to protect traditional knowledge – The Biodiversity Act and the Traditional Knowledge Digital Library and questions whether the legal regime in place gives effect to the intended purpose. It then reviews the contents of the Protection of Traditional Knowledge Bill, 2022 and demonstrates how this bill together with *sui generis* systems may be able to manage traditional knowledge preservation effectively. The paper ends by providing recommendations to ensure positive protection of traditional knowledge against biopiracy by creating awareness and enhancing the ability of indigenous communities to safeguard traditional knowledge for benefit-sharing.

**Keywords:** traditional knowledge, biopiracy, indigenous communities, *sui generis*

## II. Research Problem

Due to the intangible and collective nature of TK, its preservation and protection against biopiracy become really challenging. Biopiracy deprives people who own indigenous knowledge of the benefits they get since it does not seek their consent, nor does it give them a fair share of the benefits derived. Even though there are laws that prevent biopiracy, the vice is prevalent. This is because existing laws afford protection in a defensive manner, and no

framework has been adopted towards the positive protection of TK from biopiracy. The research problem lies in identifying the limitations of the existing framework regarding the protection offered to TK against biopiracy. This includes further analysis into potential better mechanisms that could exist in the form of *sui generis* systems guaranteeing fair benefitsharing.

## III. Research Objectives

- To analyze the incidence of biopiracy in India with reference to certain cases
- To critically review the present legal structure for protection of traditional knowledge from biopiracy
- To identify lacunas in the present legal framework about protection of TK from biopiracy
- To develop recommendations towards enriching the positive protection of TK in India, including a *sui generis* system

## IV. Research Methodology

The research methodology adopted for this study is a doctrinal study with a qualitative approach that incorporates the analysis of existing literature, which includes research papers and articles, relevant statutes, and official reports published by the government as well as WIPO to consider the effectiveness of the current legal framework in curbing biopiracy. Articles by Indian authors as well as non-Indian origins have been referred to bring forward different perspectives on the issue. AI tools have been applied for the structuring of the research and for language refinement while adhering to strict research ethics and guidelines.

## 1. Introduction

Traditional knowledge or TK refers to the living body of knowledge, skills and practices owned and grown collectively by a community. It therefore forms an important part of the cultural and spiritual heritage of the community because it is passed on to the future generation. TK finds a place in many spheres and fields - including agriculture, medicine, scientific research and biodiversity.[1]

[1] WIPO, https://www.wipo.int/tk/en/tk (last visited Oct. 8, 2024).

India has a rich biodiversity, with 7-8% plant and animal species known worldwide.[2] The native plant species are of huge importance in traditional medicine systems, such as Ayurveda, Siddha, Naturopathy, Yoga, Unani, followed by the tribes and indigenous communities of India. So, the protection, preservation, and promotion of traditional knowledge are greatly important for India because of the huge economic potential it holds.[3]

Another disturbing trend that can be noted concerning TK is biopiracy. Biopiracy has been defined as the unauthorized use and patenting of genetic resources or traditional knowledge. It is done without the consent of the countries or communities that hold the right to such knowledge.[4] Despite some international agreements on the subject, cases of biopiracy associated with medicinal plants grown in India have occurred. Examples include neem, turmeric, phyllanthus amarus (bhumi amalaki), and other plants that are derived from Indian indigenous groups' traditional knowledge and have received patents in the US.[5] Communities, therefore, become more susceptible to exploitation because their information is plundered and misappropriated without consent or proper recompense for the communities.

## 2. Traditional Knowledge as property

Since traditional knowledge is owned communally and not individually and since one single inventor or owner of such knowledge cannot be traced, it presents a unique challenge to the concepts of property and ownership. Traditionally, jurisprudence had dealt with the concept of property in terms of rights to possess, use, and dispose of assets that are either corporeal (tangible) or incorporeal (intangible). TK is the sum of information existing in oral traditions, practices, and customs, and therefore it becomes intangible.

Generally ownership over property is acquired by creation (original) or transfer (derivative). In this case, the creator of traditional knowledge cannot be traced back since it has been passed on orally as a customary practice and is not codified. Coming to the second option - ownership can be acquired derivatively as well. So, traditional knowledge can be characterized as *res*

[2] CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/countries/profile?country=in (last visited Oct. 8, 2024).
[3] *See* Naina Gupta, *Traditional Knowledge and Biopiracy in India*, SOCIAL & POLITICAL RESEARCH FOUNDATION (Jun. 16, 2020), https://sprf.in/wp-content/uploads/2021/02/16.6.2020_Traditional-Knowledgeand-Bio-Piracy-in-India.pdf
[4] WTO, https://www.wto.org/english/tratop_e/trips_e/trips_issues_e.htm (last visited Oct. 8, 2024).
[5] *See* Vandana Shiva, *Biopiracy From Neem to Rice to Atta! Gates and Monsanto Influence IPR Policy*, THE CITIZEN (Oct. 8, 2024), https://www.thecitizen.in/index.php/en/NewsDetail/index/1/7840/Biopiracy-FromNeem-to-Rice-to-Atta-Gates-and-Monsanto-Influence-IPR-Policy.

*communis* and viewed as communal property transferred within a group of people from one generation to another and owned together by that entire group of people. Traditional knowledge has grown because of the contribution of numerous individuals through multiple generations, and cannot be viewed apart from the community's cultural identity and heritage.

This means that rights in the control, management of such property should be envisaged from the perspective of the community as a whole and not from the perspective of an individual alone in the community. Instead of viewing this knowledge as a commodity which is employed only for unbalanced monetary advantages, decisions need to be undertaken in the interest of this knowledge so that it is kept and safeguarded with the intent to maintain the cultural heritage of the community. However, the intangible and uncodified character of TK makes protection from biopiracy difficult.

Biopiracy is the unauthorized exploitation and patenting of traditional knowledge in disregard to the rightful owners. Biopiracy exploits the loopholes inherent in the communal ownership model of TK by allowing third parties to exploit indigenous knowledge for their benefits without fair compensation. This call for addressing biopiracy therefore needs to be made protecting the integrity and rights of communities over traditional knowledge.

## 3. Cases of biopiracy

3.1 Turmeric

A patent was granted to two non-resident Indians from the University of Mississippi Medical Center by the US Patent and Trademark Office (USPTO) for the "Use of Turmeric in Wound Healing." This patent raised a lot of eyebrows after it was contested in India by the Council for Scientific and Industrial Research (CSIR). In response, the CSIR contended that the invention was not new because the healing property of turmeric had been intuitively assumed by the Ayurvedic practitioners for a long time, and the therapeutic use of turmeric was recorded in Indian history more than hundreds of years ago. They produced sources of traditional knowledge from ancient Sanskrit texts as well as a publication in the Journal of the Indian Medical Association from 1953 to support their argument. The USPTO rejected six claims for the patent and declared it invalid based on grounds of non novelty.[6]

[6] *See* Sangeeta Udgaonkar, *The recording of traditional knowledge: Will it prevent 'bio-piracy'?*, 82 CURRENT SCIENCE 413, 414 (2002).

3.2 Neem

The US Department of Agriculture (USDA) and WR Grace acquired patent rights for an extraction technique of neem oil, particularly for its fungicidal properties. WR Grace further secured patents for neem-based biopesticides, including Neemix, designed for agricultural use. In India, RFSTE joined hands with IFOAM to campaign against the above patent claiming that it is known to every Indian for over one thousand years that neem works as a fungicide, an insect repellent and used in soap making. The EPO then canceled the patent due to the absence of originality in the so-called invention.[7]

3.3 Basmati Rice

Several patents were granted by the USPTO to RiceTec Inc. of Texas for Basmati rice lines and grains. A Public Interest Litigation was lodged in the Supreme Court of India by the Research Foundation of Science, Technology and Ecology against the patent possessed by RiceTec Inc. on the basmati rice for the interests of rice traders in India. They contended that Basmati rice can only grown in the Indo-Gangetic plains of India owing to certain climatic conditions and genetic encoding. The government sought a re-examination of the validity of the patent at USPTO. The situation became a diplomatic battle between the US and India, as India threatened to get the case adjudicated by WTO for violation of TRIPS. Finally, 15 out of 20 claims were withdrawn from the first patent application, and it was a great victory for Indian rice traders.[8]

## 4. Legal framework for TK and biopiracy

Incorporeal property like traditional knowledge can be protected in two ways.

(i) defensive protection - preventing external entities from obtaining intellectual property rights over traditional knowledge

(ii) positive protection - empowering communities to control and benefit from their traditional knowledge through existing intellectual property systems or specific legislation[9]

[7] *See* Iti Chauhan, *India- Victim of Biopiracy*, 4 INDO AMERICAN J.L. PHARMA RESEARCH 329, 331-332 (2014).
[8] *Id.* at 331.
[9] WIPO, https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf (last visited Oct. 8, 2024).

4.1 International framework

WIPO is a UN agency which strives to promote innovation throughout the world by having an international IP system. The Patent Cooperation Treaty, founded under WIPO, harmonizes application procedures for patents but does not issue patents internationally. PCT sets requirements - including novelty, inventive step, and industrial applicability.[10] Member countries may employ extra or different requirements in awarding national patents. The Patent Law Treaty has an objective of making it user-friendly by integrating national procedures for patents.[11]

With respect to the TRIPS Agreement, though its main target is to promote international trade, at the same time it protects IPR. Article 27 is especially controversial since it holds the patentable subject matters as including life forms.[12] Sui generis systems,[13] of course, could exercise some flexibility while requiring patent protection for microorganisms as well as nonbiological processes, thereby making it difficult to resolve biopiracy.[14]

4.2 Indian framework

The Biological Diversity Act, 2002[15] facilitates protection of biological diversity and fair and equitable sharing of benefits derived from biological resources. The legal framework that this Act provides has two components. The first one mandates obtaining prior informed consent prior to utilizing or accessing any biological resource or traditional knowledge. The second component maintains that all resource users are subject to the regulation of the establishment of the National Biodiversity Authority and access to the resources will be in a manner that there is equitable distribution of the benefits accrued from the resources.

The Protection of Plant Varieties and Farmers' Rights Act, 2001 also has such provisions in the sense that it recognizes the contribution of the agricultural community in preserving and improving the plant genetic resource and makes the inclusion of a compensation scheme for

[10] Patent Cooperation Treaty, June 19, 1970. 28 U.S.T. 7645; 1160 U.N.T.S. 231; 9 I.L.M. 978 (1970).

[11] *See* Deepthi Rodda, *Biopiracy Analysis of Existing International and Indian Legal FrameWork*, 3 INT'l J.L. MGMT. & HUMAN. 227, 231-232 (2020).

[12] Agreement on Trade-Related Aspects of Intellectual Property Rights: April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[13] A sui generis system in IPR refers to a specialized legal framework designed to address specific categories of IP that may not be adequately protected by existing framework of IP laws.

[14] *supra* note 10, at 232-233.

[15] The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003 (India).

such usage.[16]

The TKDL project is a collaborative project involving CSIR, Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare. This is composed of an expert team including specialists in traditional medicine, IT and patent offices, scientists and technical personnel. It captures traditional knowledge relating to Ayurveda, Unani, Siddha and Yoga, which is in the public domain, using digital technology in a language that can be understood by international patent examiners. In this way even prior conflicting art can be presented without the risk of ambiguity that may arise when the patent examiners' language is relied on.[17]

4.3 Protection of Traditional Knowledge Bill, 2022

The Protection of Traditional Knowledge Bill, 2022 was introduced in Lok Sabha in April 2022 by MP Shashi Tharoor. The legislation defines the ownership rights to TK of the appropriate government and recognizes indigenous communities as the custodians with license for both commercial and non-commercial use.[18] The bill also outlines the collective rights for developing TK and benefit sharing of members.[19]

Further, the bill provides defensive protection to TK by prohibiting patents or IP protection on TK obtained from India with certain exceptions.[20] It also penalizes misappropriation of TK and gives certain civil remedies like fines for those affected by the same.[21]

Hence, the bill provides a clear definition of traditional knowledge and also specifies ownership and associated rights. It affirms the exclusive right of the Union of India over traditional knowledge within the territory. Ownership is granted to the government of that state where that traditional knowledge is practiced. In case of more than one state, joint ownership is conferred upon the respective governments with equal and undivided claims and interests.[22] However it has not been passed and no action has been taken in this regard yet.

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[16] *See* Guest, *Biopiracy in India: Exploring the Laws and Regulations to Protect Traditional Knowledge and Biodiversity*, LEGALLY FLAWLESS (Oct. 8, 2024), https://legallyflawless.in/biopiracy-in-india-exploring-thelaws-and-regulations-to-protect-traditional-knowledge-and-biodiversity/.

[17] WIPO, https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html (last visited Oct. 8, 2024).

[18] The Protection of Traditional Knowledge Bill, 2022, No. 87, § 3 (India).

[19] The Protection of Traditional Knowledge Bill, 2022, No. 87, § 4 (India).

[20] The Protection of Traditional Knowledge Bill, 2022, No. 87, § 8 (India).

[21] The Protection of Traditional Knowledge Bill, 2022, No. 87, § 9 (India).

[22] The Protection of Traditional Knowledge Bill, 2022, Bill No. 87 of 2022.

## 5. Limitations in the existing legal framework

The existing IP laws such as Patent Act and Copyright Act do not fit well in protecting TK. One express provision that supports this is Section 3(j) of the Patents Act that does not grant patents for plants and microorganisms.[23] Also, Section 3(p) of the Patents Act states that traditional knowledge cannot be considered a novel or innovative invention.[24]

The Biodiversity Act, 2002, has a restricted scope - it primarily deals with regulations relating to access of biological resources and benefit-sharing. But the scope may not suffice in order to address biopiracy of associated TK. The act requires the registration of biological resources as well as the related knowledge. This process would become cumbersome for communities since most of these communities do not have formal documentations of their knowledge.

Though a huge achievement in codification of indigenous knowledge and prevention of biopiracy, the TKDL can unintentionally become an abettor to biopiracy. The proposed electronic library can enable companies to simply identify easy commercial applications of medicinal and therapeutic properties available in the database. Such slight variation or improvement will suffice to get the patent approval.[25] It may enhance vulnerability by allowing multinational companies to commercially exploit TK as an absolutely new innovation. Companies which are looking for uncompetitive gains can exploit traditional knowledge by filing for a majority of patents by simply rebranding old knowledge into new ones, and TKDL acts as a conduit for the same. This will enable corporate appropriation of threatened and indigenous knowledge, which directly threatens the basic and economic rights of traditional communities to practice their indigenous knowledge.[26]

## 6. Sui generis system for TK

Sui generis denotes something that is unique. It goes beyond the fixed boundaries of an IP system and incorporates other elements particular to the subject-matter, into the system so as to fit it perfectly.[27]

[23] The Patents Act, 1970, No. 39, § 3 cl. j, Acts of Parliament, 1970 (India).
[24] The Patents Act, 1970, No. 39, § 3 cl. p, Acts of Parliament, 1970 (India).
[25] *See* Devinder Sharma, *Digital Library on Indian Medicine Systems: Another Tool for Biopiracy*, 37 ECO & POL WEEKLY 2416 (2002).
[26] *supra* note 7.
[27] *See* Balavanth S Kalaskar, *Traditional Knowledge and Sui-Generis Law*, 3 INT'l J.L. SCIEN. & ENGG. RESEARCH. (2012).

Traditional knowledge is often communal, oral, and lacks a single owner. Communities may not be equipped with the documentation or formal registration required to establish ownership of TK under current IP laws. This makes it difficult to fit TK into the individualistic ownership model of patents.[28] *Sui generis* systems are legal frameworks tailored to the unique characteristics of TK, offering greater flexibility and recognition of community ownership.

In the context of biopiracy of TK, the existing laws and policies do not provide positive protection to TK. There is a need for tailor-made systems to fit this particular area of IP. Thus, the *sui generis* system incorporates elements of intellectual property law, equitable benefit sharing provisions, customary law, rights of indigenous communities, prior informed consent and contractual agreements and represents the most comprehensive system for safeguarding Traditional Knowledge. It aims for broader utilization of indigenous and local communities' knowledge, innovations, and practices while involving the holders of such knowledge.[29]

However, international recognition is crucial for the effective implementation of sui generis systems at the national level.[30]

The WIPO has identified the following essential elements for a sui generis system to be effective.[31] These have been correlated with the protection of TK as follows -

| **Sl. No.** | **Element of *sui generis* system** | **With respect to traditional knowledge** |
|---|---|---|
| 1 | Policy objective of the protection | Prevent biopiracy, ensure fair benefit-sharing |
| 2 | Subject matter of the protection | Traditional knowledge - medicinal knowledge, agricultural practices |
| 3 | Criteria for protection | Must be collective, culturally significant, passed through generations |
| 4 | Owner of the rights | Indigenous communities |
| 5 | Acquisition of the rights | Communal ownership, recognition by an authorized body (NATK) |

[28] *Id.*
[29] WIPO, https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_3/wipo_grtkf_ic_3_8.pdf, (last visited Oct. 8, 2024).
[30] *supra* note 27.
[31] *supra* note 29.

| | | |
|---|---|---|
| 6 | Administration and enforcement | NATK and State Boards manage compliance, legal actions, benefit-sharing |
| 7 | Expiration of rights | Not applicable - Perpetual protection as long as knowledge is in use |

## 7. Suggestions and recommendations

It can be observed that the existing legal framework in India only acts as a defensive mechanism to prevent the misuse of traditional knowledge. There is currently a lack of specific legislation dedicated solely to the positive protection of TK. The Protection of Traditional Knowledge Bill aims to "acknowledge the rights of those who possess and generate Traditional Knowledge, establish a National Authority to support them, and combat misappropriation by others."[32]

Also, the bill acknowledges the contributions of specific communities to the development of traditional knowledge by granting them certain rights, including the right to selfdetermination.[33] Hence, it can act as a positive protection for traditional knowledge if passed.

Another suggestion is to include a provision in the bill for the international recognition and cooperation of a sui *generis* system of TK. This can be along the lines of the government pursuing the international recognition of the sui generis system in relevant international forums like WIPO and WTO. It can also include a clause for the government to negotiate bilateral and multilateral agreements to prevent the misappropriation of Indian traditional knowledge in foreign jurisdictions and to facilitate cross-border enforcement of benefit-sharing agreements.

Another thing that must be considered is to implement proper safeguards in the TKDL so that it is inadvertently not an open access that corporations can misuse and misappropriate. Also, increasing public awareness about the importance of TK and the threats of biopiracy can act as an effective measure to control biopiracy. Indigenous communities must be educated about their rights so that they are empowered to participate in the protection of their traditional knowledge.

[32] The Protection of Traditional Knowledge Bill, 2022, Bill No. 87 of 2022.
[33] *Id.*

## 8. Conclusion

Thus, the intangible and collective nature of traditional knowledge conflicts head-on with the traditional models of ownership of IP laws and biopiracy thrives on such very issues and gaps. India has moved one step ahead through the Biodiversity Act and the TKDL project, but limitations again prevail. The Protection of Traditional Knowledge Bill brings hope in by the establishment of National Authority but remains unfulfilled without any promise so far. Engagement with *sui generis* systems specifically designed for TK can be more flexible and more responsive to community ownership. However, it is under international recognition that these can be made effective at the national level. By these recommendations, India can take a step further towards the legal framework where TK is protected, and indigenous communities empowered to preserve their traditional knowledge systems for a long time.

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