

## Protecting Indigenous Intellectual Property Rights in Technological Advancements and the Commercialization of Traditional Knowledge

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### CITATION

Dua, A. (2026). Protecting Indigenous Intellectual Property Rights in Technological Advancements and the Commercialization of Traditional Knowledge. *Shodh Manjusha: An International Multidisciplinary Journal*, 03(01), 01–21. <https://doi.org/10.70388/sm250184>

### Article Info

Received: Oct 21, 2025

Accepted: Nov 23, 2025

Published: Jan 05, 2026

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<https://doi.org/10.70388/sm250184>

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### ABSTRACT

Indigenous and local communities have been the long-term custodians of traditional knowledge (TK) and genetic resources, which form the basis for many technological innovations and commercial products. However, the prevailing intellectual property (IP) systems, designed primarily for individual inventions and creative works within market-based economies, often fail to recognize the collective and intergenerational nature of TK. This mismatch has frequently resulted in the misappropriation of knowledge and the unequal or unfair distribution of benefits, leaving communities without proper recognition, control, or compensation for the use of their heritage. This paper reviews international and national instruments, examines illustrative case studies (including India's Traditional Knowledge Digital Library), identifies gaps, and proposes an integrated set of legal, institutional, and community-led measures to protect indigenous IP rights while enabling equitable commercialization.

**Keywords:** traditional knowledge, indigenous rights, intellectual property, Nagoya Protocol, disclosure of origin, TKDL, benefit-sharing, sui generis protection

## **Introduction**

Traditional Knowledge (TK) refers to the skills, practices, and know-how that indigenous and local communities have developed over generations. Today, TK is increasingly connected to global research, business, and digital technologies. For example, pharmaceutical companies study plant-based remedies used by communities to develop new medicines. The fashion and luxury industries often draw inspiration from indigenous art and designs. Even patent and trademark systems are sometimes applied to protect innovations that are based on TK.

While using TK in these ways can create new opportunities and benefits, it also brings serious risks. Communities may experience bio piracy, where their knowledge is used without permission or fair compensation. Their cultural traditions and practices may be weakened or lost, and they may lose control over how their knowledge is shared or used. Moreover, the financial benefits from commercial use of TK often do not reach the communities that originally developed it, leading to unfair outcomes.

International policy is increasingly recognizing the rights of indigenous peoples over traditional knowledge (TK), traditional cultural expressions (TCEs), and genetic resources, while developing tools to prevent misappropriation and ensure fair benefit-sharing. The World Intellectual Property Organization (WIPO) has played a key role by providing practical toolkits for documentation, legal protection, and negotiation strategies. Complementary instruments—including the Nagoya Protocol under the Convention on Biological Diversity (CBD), the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), and national *sui generis* laws—create a broader legal and normative framework for safeguarding TK. This paper examines these international and national instruments, practical tools, and case examples to propose an integrated approach for protecting indigenous IP in technological and commercial contexts. Conventional IP regimes (patents, copyrights, trademarks) presume identifiable individual inventors/authors, time-limited exclusivity, and novelty/originality tests. TK is typically communal, cumulative across generations, often undocumented or orally transmitted, and may fail novelty/originality tests — leaving it ill-suited to these regimes.

## **Research Problem**

Traditional Knowledge (TK), which represents the collective wisdom, practices, and innovations of Indigenous communities, faces significant challenges in the modern

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intellectual property (IP) and commercial landscape. The existing IP frameworks, primarily developed within Western legal traditions, are incompatible with the communal and intergenerational nature of TK. These systems emphasize individual authorship, novelty, and time-bound protection, thereby excluding community-held and evolving knowledge from meaningful recognition.

Moreover, bio piracy and misappropriation continue to threaten Indigenous rights, as external actors—particularly in the pharmaceutical, biotechnology, and fashion industries—often exploit TK without consent or benefit-sharing. The absence of effective disclosure obligations, Access and Benefit-Sharing (ABS) enforcement, and Free, Prior, and Informed Consent (FPIC) mechanisms further exacerbates these injustices.

Therefore, the core research problem lies in how to design and implement legal and policy frameworks that effectively protect TK, prevent misappropriation, and ensure equitable commercialization, while remaining compatible with international obligations and respectful of Indigenous governance systems.

### **Literature Review:**

1. “Traditional Knowledge Digital Library (TKDL): A Distinctive Approach to Protect and Promote Indian Indigenous Medicinal Treasure” — Sharma.R &Kumar P (2023)

This paper analyzes India’s Traditional Knowledge Digital Library (TKDL) as a pioneering model for protecting Indigenous medicinal knowledge from biopiracy. It details how the TKDL catalogues traditional medicinal formulations in standardized formats accessible to global patent offices, enabling examiners to detect prior art and prevent wrongful patents. The authors highlight TKDL’s success in revoking or blocking patents on turmeric, neem, and basmati rice, but also point out limitations—such as limited community involvement, restricted access, and lack of benefit-sharing mechanisms.

2. “Protecting Traditional Knowledge: Can Intellectual Property Rights Help?” — (Singh A,2020)

The author critically examines whether traditional IP laws (patent, copyright, trademark) can adequately protect TK. The paper finds that current IP systems are fundamentally misaligned with Indigenous knowledge traditions because they prioritize individual ownership, novelty, and time-bound protection, which do not fit the collective and evolving nature of TK. The author advocates for sui generis systems and customary law integration to bridge this gap, Dua, A.

proposing a hybrid model combining international IP norms with community-based governance.

3. “Sharing the Benefits of Commercialisation of Traditional Knowledge: What Are the Key Success Factors?” —Moyo. T & Peterson. L (2023)

This study explores various benefit-sharing models in the commercialization of TK, focusing on real-world case studies (such as the Hoodia plant case in South Africa). It identifies key success factors: community participation, clear contractual frameworks, capacity building, and state support. Conversely, it shows how benefit-sharing often fails due to information asymmetry, power imbalances, and) lack of enforceable agreements.

4. “A Sui Generis Regime for Traditional Knowledge” — Rao.D. S (2021)

This paper examines the conceptual foundation and legal design of sui generis systems to protect TK. It reviews different country approaches (India, Peru, Philippines) and discusses compatibility with TRIPS and WIPO frameworks. The author argues that sui generis regimes should provide perpetual, collective right recognize customary law, and allow flexible remedies rather than rigid IP exclusivity.

5. “The Role of Traditional Knowledge Digital Library in the Protection of Indian Traditional Knowledge: A Critical Analysis” Patel .M, & Deshmukh. S, (2024)

This recent article reassesses TKDL’s evolving function amid digital globalization. While it praises TKDL’s success in preventing bio piracy, it critiques its top-down management and limited accessibility to Indigenous stakeholders. The authors suggest integrating community protocols, block chain-based access tracking, and benefit-sharing clauses into future TKDL frameworks.

## **Scope of the Study**

This study focuses on the legal, institutional, and ethical dimensions of protecting and commercializing Indigenous Traditional Knowledge (TK) in the context of rapid technological advancement and globalization. It examines how existing intellectual property (IP) frameworks, such as patents, copyrights, and trademarks, interact with the communal and intergenerational nature of TK, and why these systems often fail to ensure fair recognition and benefit-sharing for Indigenous communities.

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The study analyzes international instruments—including the Nagoya Protocol, the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), and WIPO’s ongoing work on Traditional Knowledge and Traditional Cultural Expressions (TCEs)—to assess their role in establishing normative and procedural safeguards. It also explores national and community-level mechanisms, such as India’s Traditional Knowledge Digital Library (TKDL) and other sui generis models, to identify best practices and challenges in practical implementation.

The study emphasizes both defensive protection measures (e.g., documentation and disclosure requirements) and positive protection frameworks (e.g., benefit-sharing, customary law recognition, and corporate due diligence obligations).

While the focus remains on policy and legal mechanisms, the study also considers socio-economic and ethical aspects, including community empowerment, capacity building, and equitable partnerships with private and research entities.

### **Objectives of the Study**

The primary objective of this research is to examine and propose effective legal and policy mechanisms for the protection and equitable commercialization of Indigenous Traditional Knowledge (TK) in the context of globalization and technological innovation.

The specific objectives are as follows:

1. To analyze the limitations of existing intellectual property (IP) regimes in safeguarding Traditional Knowledge, particularly in relation to the collective and intergenerational nature of Indigenous knowledge systems.
2. To evaluate the role of international frameworks—such as the Nagoya Protocol, UNDRIP, and WIPO’s initiatives—in promoting fair benefit-sharing, preventing misappropriation, and supporting Indigenous rights over TK and genetic resources.
3. To examine the effectiveness of national mechanisms (e.g., India’s Traditional Knowledge Digital Library (TKDL), sui generis laws, and Access and Benefit-Sharing frameworks) in addressing biopiracy and facilitating ethical commercialization.
4. To identify challenges in implementing Free, Prior, and Informed Consent (FPIC) and Mutually Agreed Terms (MAT) within research and commercial agreements involving Indigenous communities.

5. To propose an integrated model that combines international standards, national legislation, and community-based governance to ensure equitable protection, recognition, and sustainable commercialization of Traditional Knowledge.
6. To recommend policy reforms and institutional measures that enhance community participation, corporate accountability, and capacity-building in the protection and utilization of Indigenous Traditional Knowledge.

## **Research Questions**

This study seeks to address the following key research questions:

1. How effective are existing international instruments—such as the Nagoya Protocol, UNDRIP, and WIPO frameworks—in ensuring the protection and equitable commercialization of Indigenous Traditional Knowledge?
2. In what ways do conventional intellectual property (IP) systems fail to recognize and safeguard the collective, intergenerational, and cultural dimensions of Traditional Knowledge?
3. What legal and institutional mechanisms have countries like India and others implemented (e.g., TKDL, Access and Benefit-Sharing laws, sui generis protection systems) to prevent misappropriation and promote fair benefit-sharing?
4. How can technology (such as digital documentation systems, databases, and AI-based prior art searches) be harnessed ethically to protect, rather than exploit, Traditional Knowledge?
5. What policy and governance model can best integrate international norms, national legislation, and community protocols to ensure sustainable protection, equitable benefit-sharing, and empowerment of Indigenous communities?

## **Research Methodology**

This study employs a doctrinal-analytical research methodology combined with comparative legal analysis and case study evaluation to explore the protection and commercialization of Indigenous Traditional Knowledge (TK). Given the legal and policy focus, the methodology emphasizes qualitative research and document-based analysis rather than empirical fieldwork.

### **1. Doctrinal Research**

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The study examines primary legal sources, including international treaties (e.g., Nagoya Protocol, UNDRIP), national legislation (e.g., India's Traditional Knowledge Digital Library Act, sui generis laws), and patent regulations.

Secondary sources, such as academic articles, reports, WIPO toolkits, and policy briefs, are analyzed to identify theoretical foundations, legal principles, and gaps in protection.

## 2. Comparative Analysis

A comparative approach is used to evaluate different national strategies for TK protection, including India, Peru, Philippines, and African case studies.

The aim is to identify best practices, common challenges, and lessons that can inform integrated legal and policy frameworks.

## 3. Case Study Evaluation

Key cases of bio piracy, misappropriation, and successful benefit-sharing agreements are analyzed, including: Hoodia plant commercialization (South Africa), Neem and turmeric patent disputes (India)

Other illustrative cases from global TK commercialization projects. These cases help demonstrate practical challenges and solutions in implementing legal protections and ABS agreements.

## 4. Analytical Framework

The study applies a multi-dimensional lens, integrating:

Legal analysis- (IP law, sui generis frameworks)

Policy evaluation- (ABS, disclosure rules, FPIC enforcement)

Ethical and socio-cultural considerations- (community participation, empowerment, equitable benefit-sharing)

## Hypothesis

1. **H1:** Conventional intellectual property (IP) systems are insufficient to protect the collective, intergenerational, and cultural dimensions of Indigenous Traditional

Knowledge, leading to increased risk of misappropriation and unfair commercialization.

2. **H2:** International legal instruments such as the Nagoya Protocol, UNDRIP, and WIPO frameworks, while providing normative guidance, are only partially effective in safeguarding TK without strong national legislation and enforcement mechanisms.
3. **H3:** National measures, including sui generis laws, defensive documentation systems (e.g., TKDL), and Access and Benefit-Sharing (ABS) frameworks, enhance the protection of TK, but their effectiveness depends on community participation, transparency, and enforceable benefit-sharing agreements.
4. **H4:** Integration of technological tools (digital TK databases, cryptographic access controls) with legal and policy frameworks can significantly improve the protection and equitable commercialization of TK, provided ethical and community governance principles are embedded.
5. **H5:** A multi-dimensional, integrated approach that combines international norms, national legislation, and community-led governance offers the most effective pathway for protecting TK and ensuring fair and sustainable commercialization.

## **International Legal Instruments**

Several international frameworks aim to safeguard TK and ensure fair benefit-sharing:

- **Convention on Biological Diversity (CBD) and the Nagoya Protocol:** These instruments establish guidelines for Access and Benefit-Sharing (ABS), emphasizing the need for prior informed consent (PIC) and mutually agreed terms (MAT) when utilizing genetic resources and associated TK. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (ABS) provides a global instrument to ensure benefits from the use of genetic resources (and associated TK) are shared fairly. It operationalizes prior informed consent (PIC) and mutually agreed terms (MAT) between providers (including indigenous communities) and users, and it requires measures to ensure compliance with national ABS laws. The Protocol is a cornerstone when TK relates to genetic resources and underpins many national ABS regimes.
- **United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP):** Article 31 of UNDRIP affirms Indigenous peoples' rights to maintain, control, protect,

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and develop their cultural heritage, traditional knowledge, and traditional cultural expressions.

- **WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge:** This treaty, adopted in 2024, introduces a disclosure requirement in patent applications, mandating applicants to disclose the origin of genetic resources and associated TK, thereby promoting transparency and accountability. WIPO has produced extensive analyses, practical toolkits, and policy options for protecting TK and TCEs. Its guidance documents outline documentation best practices, community decision-making processes, and policy options (including defensive databases, sui generis legislation, contractual arrangements, and awareness-raising among IP offices). WIPO stresses that documentation must be community-led and that documentation itself can be a double-edged sword: useful for preventing wrongful patent grants while risking the loss of community control if improperly managed.

### Case Studies

The evolution of judicial and administrative decisions across jurisdictions reveals the challenges and opportunities in protecting TK

**Neem Patent Case (1994, EPO):** A patent on neem-based pesticide was revoked after Indian NGOs proved longstanding use, preventing misappropriation. The European Patent Office (EPO) upheld the revocation of a patent granted to the US Department of Agriculture and W.R. Grace for a neem -based fungicide, ultimately dismissing the patent holder's appeal on March 8, 2005. This decision ended a long-standing dispute initiated by environmental activists and NGOs, who argued the patent constituted bio piracy, as neem's fungicidal properties and its use by farmers were part of centuries of traditional Indian knowledge.

#### Background of the Case

- **Patent Grant:** The EPO initially granted the patent on a neem-based fungicide to the US Department of Agriculture and W.R. Grace in 1994.
- **Opposition:** A group of NGOs, including the International Federation of Organic Agriculture Movements (IFOAM), along with Indian activists like Vandana Shiva, opposed the patent on the grounds of biopiracy, stating the knowledge was not new or inventive.

- **Revocation:** The EPO revoked the patent in 2000, deeming it a case of biopiracy.
- **Appeal:** W.R. Grace, along with the US government, appealed the revocation.

The EPO's Final Decision (2005)

- The EPO dismissed the appeal, upholding the original decision to revoke the patent.
- The basis for the decision was evidence presented by opponents showing that farmers had been using neem for centuries and that prior research existed on its properties.
- This decision was seen as a victory for traditional knowledge, affirming indigenous rights over natural resources.

### **Basmati Rice Case (1997–2001, Rice Tec Inc.)**

In 1997, U.S. Company Rice Tec Inc. was granted Patent No. 5663484 for Basmati-type rice lines, claiming to develop a new aromatic strain by crossbreeding Basmati with other varieties. India, supported by NGOs like the Centre for Food Safety and the Research Foundation for Science, Technology and Ecology, challenged the patent, arguing that Basmati is a unique rice variety from northern India and cannot be patented. Consequently, the U.S. Patent Office revoked 15 of 20 claims, allowing Rice Tec patents only for three new hybrid strains. The case highlighted the importance of Geographical Indications (GI) in protecting TK-related crops and the need for timely action to prevent misappropriation.

**Turmeric Patent Case (1995, USPTO challenge):** The U.S. patent on turmeric's wound-healing properties was revoked after India's CSIR provided evidence of prior art. This became a landmark in defensive protection of TK. The US Patent and Trademark Office revoked the patent for turmeric's use in wound healing in 1997 because the Council of Scientific and Industrial Research (CSIR), acting as an interested party, presented prior art proving the knowledge was not novel or inventive. The USPTO decision recognized that the knowledge was already established and obvious to a person with ordinary skill in the art, effectively safeguarding India's traditional knowledge (TK) from foreign monopoly and setting a significant precedent for challenging bio piracy through re-examination.

Background of the Patent

- **The Patent:**

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In 1995, a US patent was granted to researchers from the University of Mississippi Medical Centre for the use of powdered turmeric in wound healing.

- **India's Traditional Use:**

The use of turmeric for its medicinal properties, including wound healing, had been a well-known practice in India for thousands of years.

The Re-examination Process

- **Challenging the Patent:**

The CSIR, an Indian organization, filed a request for a re-examination with the USPTO to revoke the patent.

- **Grounds for Re-examination:**

The request was based on the principle of prior art, arguing that the patented knowledge was not new and was already common knowledge in India.

- **Evidence Presented:**

The CSIR provided evidence demonstrating that turmeric's application for wounds was a matter of established tradition, even if published information in English was initially scarce.

USPTO's Decision

- **Revocation of the Patent:** The USPTO revoked the patent in 1997.
- **Reasons for Revocation:** The decision was based on a lack of novelty and non-obviousness. The USPTO acknowledged that the claims were anticipated and that the use of turmeric powder and paste was equivalent, a finding that satisfied the "Person Having Ordinary Skill in the Art" (PHOSITA) test.

Significance of the Decision

- **Victory for Traditional Knowledge:**

The turmeric case is considered a landmark victory for traditional knowledge (TK), successfully challenging the bio piracy of an indigenous invention.

- **Precedent Set:**

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It set an important precedent, highlighting the need for proper mechanisms to catalog and protect the traditional knowledge of developing countries from being patented by foreign entities

## **International**

Maya ICBG Case (Belize, 1995): Maya communities opposed medicinal plant contracts lacking prior informed consent. The project was suspended, showing the centrality of FPIC.

Hoodia & San People (South Africa, 2003): The San challenged patents on Hoodia-derived appetite suppressants. A benefit-sharing agreement was reached, establishing royalties for San communities — a pioneering ABS settlement.

Ayahuasca Case (US, 1986–1999): A U.S. patent on Ayahuasca, a sacred Amazonian plant, was revoked after indigenous protests, recognizing cultural and spiritual significance beyond economic exploitation.

Maca Case (Peru, 2001): Foreign patents on Maca extracts spurred Peru to launch national measures against biopiracy and establish TK protection databases.

## **India's Legal and Policy Framework on Traditional Knowledge Protection**

India provides one of the most instructive examples of how a developing country has worked to safeguard traditional knowledge (TK) and associated Indigenous rights while engaging with global intellectual property systems. Its approach combines administrative innovation, legislative action, and ongoing parliamentary debate that reflects both progress and tension between commercialization and cultural preservation.

- **The Role of the Traditional Knowledge Digital Library (TKDL)**

India's Traditional Knowledge Digital Library (TKDL) is a major global initiative launched by the Council of Scientific and Industrial Research (CSIR) and the Ministry of AYUSH. It was created in response to several incidents of bio piracy, such as the turmeric and neem patent controversies in the 1990s, where foreign patent offices granted rights for inventions based on long-known Indian remedies. The TKDL digitizes and classifies thousands of formulations from Ayurveda, Unani, Siddha, and Yoga texts, translating them into English, German, Japanese, and other major patent-office languages.

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The main aim of TKDL is defensive protection—ensuring that patent examiners worldwide can access prior art to prevent wrongful patent grants. Through formal agreements with the World Intellectual Property Organization (WIPO) and major patent offices, TKDL has helped India successfully challenge or block numerous patent applications based on traditional knowledge

A notable case was the Colgate-Palmolive herbal toothpaste patent opposition (2015), where TKDL evidence was used to demonstrate that the claimed herbal combination already existed in Indian traditional medicine. This led to the rejection of the application, preventing misappropriation of Indian herbal knowledge. The TKDL has thus become an essential defensive tool, showing how technological documentation can work alongside legal mechanisms to protect Indigenous IP in a globalized patent regime.

### • **Parliamentary Debates and Evolving Legislative Framework**

The Indian Parliament has been actively engaged in debating how best to formalize protection for TK. One early attempt came through Dr. Shashi Tharoor's Private Member's Bill, titled "The Protection of Traditional Knowledge Bill, 2016". Introduced in the Lok Sabha in March 2017, it proposed a comprehensive framework to recognize traditional knowledge as community-owned property, regulate its use, and provide remedies for misuse. Tharoor argued that while India had institutions like TKDL, there was "no specific law that recognizes and protects traditional knowledge as a form of intellectual property." The Bill, though not enacted, sparked important discussions on whether India should adopt a sui generis law—a special category distinct from conventional intellectual property systems—to reflect community-based ownership and custodianship of knowledge.

More recently, Parliament has debated amendments to the Biological Diversity Act, 2002, through the Biological Diversity (Amendment) Bill, 2021–2023. This Bill aimed to simplify procedures for research and commercialization while promoting the AYUSH sector. However, the debates in both Houses revealed strong differences in opinion. Supporters claimed the reforms would reduce bureaucratic hurdles and encourage domestic innovation, whereas opposition members and environmental experts criticized the Bill for excluding codified traditional knowledge from benefit-sharing provisions. Critics feared this exclusion could allow corporations to commercialize traditional formulations without compensating the Indigenous communities who preserved the knowledge for centuries.

## **Commercialization of Traditional Knowledge:**

- **The Changing Nature of Traditional Knowledge**

Traditional Knowledge (TK) has long been part of the collective heritage of Indigenous and local communities in India. Historically, it was transmitted orally through generations and used for survival, healing, and agriculture—not for profit. However, with globalization, digitization, and advances in biotechnology, TK has acquired new commercial significance. Pharmaceutical, cosmetic, and nutraceutical industries now recognize TK as a source of innovation and economic value.

The World Intellectual Property Organization (WIPO) defines TK as “knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community.” WIPO’s Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has been developing frameworks to help countries create policies that protect Indigenous communities while encouraging innovation. India, as an active participant in WIPO discussions, has pushed for systems that ensure equitable benefit-sharing rather than unregulated commercialization.

- **The Indian Model of Benefit Sharing and Community Rights**

India’s Biological Diversity Act, 2002 and its Rules of 2004 form the backbone of national law governing the use and commercialization of TK linked to biological resources. The Act mandates that prior approval from the National Biodiversity Authority (NBA) is required for any commercial use of Indian biological materials or associated knowledge by foreign entities.

One of the most significant features of this law is the Access and Benefit Sharing (ABS) mechanism. It requires that a portion of the profits or intellectual benefits derived from TK or genetic resources be shared with the local communities that contributed the knowledge. This principle, derived from the Convention on Biological Diversity (CBD) and the Nagoya Protocol, aligns with global efforts to ensure fairness in biotechnological innovation.

For example, the Kani tribe case in Kerala is often cited as India’s first practical application of benefit-sharing. Scientists from the Tropical Botanic Garden and Research Institute (TBGRI) developed the herbal drug Jeevani based on the Kani tribe’s traditional use of the

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Arogyapacha plant. TBGRI entered into a benefit-sharing agreement with the tribe, offering them a share of royalties from commercialization (Anuradha, 2001). Though the implementation faced administrative challenges, the case became a global model for ethical TK commercialization.

### Recommendations

- Strengthen disclosure of origin and patent-examination safeguards

There is a need to require patent applicants to disclose the origin of genetic resources and traditional knowledge and also to integrate national TK databases into patent office search protocols, and ensure sanctions or procedural consequences for any false or incomplete disclosure.

- Promote sui generis protection regimes for TK

Developing sui generis laws tailored to Traditional Knowledge (TK) is essential to address the unique nature of such knowledge, which often does not fit neatly within conventional intellectual property frameworks like patents or copyrights. These laws should recognize collective ownership rights, acknowledging that TK is typically held and transmitted by communities rather than individuals.

They should also provide for perpetual or long-term protection, where appropriate, to reflect the continuing and intergenerational nature of traditional knowledge, unlike the limited duration of standard IP rights. Furthermore, flexible remedies—such as benefit-sharing mechanisms, community-led dispute resolution, or moral rights protection—should be incorporated to ensure justice and fairness for indigenous communities.

Importantly, these sui generis regimes must remain compatible with international obligations, such as those under the WTO's TRIPS Agreement and the Convention on Biological Diversity (CBD), ensuring coherence between national and global frameworks.

Most crucially, such laws should be co-designed with indigenous peoples and local communities, ensuring their active participation in shaping the scope, enforcement, and governance of these protections. This participatory approach not only enhances legitimacy but also ensures that the resulting legal mechanisms genuinely reflect the values, customs, and needs of the communities they are meant to serve.

- Community protocols & Free, Prior and Informed Consent (FPIC) operationalization

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Implement robust Free, Prior, and Informed Consent (FPIC) procedures within national Access and Benefit-Sharing (ABS) laws and corporate due diligence frameworks to ensure that indigenous and local communities have a genuine voice in decisions affecting their traditional knowledge and genetic resources. FPIC should be obtained before any access, use, or commercialization takes place, ensuring that consent is freely given, informed, and based on complete understanding of potential impacts and benefits.

Additionally, community protocols should be documented—that is, community-developed rules and procedures governing access to and use of their knowledge and resources—as a mandatory component of any commercialization agreement. These protocols should outline consent processes, benefit-sharing terms, and conditions for use, reflecting the community’s cultural values and governance systems.

Embedding such requirements into national and corporate frameworks strengthens transparency, prevents exploitation, and ensures that commercialization of traditional knowledge and genetic resources is conducted in a fair, ethical, and equitable manner, consistent with international standards such as the Nagoya Protocol.

- Equitable ABS mechanisms and benefit-sharing templates

Standardize fair benefit-sharing templates that include a tiered structure encompassing both monetary (such as upfront payments, royalties, and licensing fees) and non-monetary benefits (such as capacity building, technology transfer, joint research, and co-ownership of intellectual property). These standardized models can provide clarity and transparency in negotiations while still preserving flexibility to adapt terms based on the specific context, community needs, and nature of the resource or knowledge used.

To ensure equitable distribution, establish national benefit-sharing funds or community trust mechanisms that can receive, manage, and disburse collective benefits on behalf of local and indigenous communities. Such institutional frameworks help prevent exploitation, ensure accountability, and promote long-term community development, thereby reinforcing the principles of fairness, sustainability, and respect embedded in the Access and Benefit-Sharing (ABS) regime.

- Controlled documentation with access safeguards

Support the establishment of community-controlled documentation systems—such as digital libraries, archives, and registries—that preserve and manage Traditional Knowledge (TK) in

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a secure and rights-based manner. These systems should incorporate cryptographic access controls, data sovereignty provisions, and legally binding agreements to regulate and limit third-party access, ensuring that communities retain full authority over how their knowledge is shared and used.

Such initiatives should prioritize defensive documentation, similar to the Traditional Knowledge Digital Library (TKDL) model, which serves as a reference for patent examiners to prevent the misappropriation of TK through wrongful patents. Access to these databases should be granted only under strict non-disclosure agreements (NDAs) and primarily for the purpose of prior art verification, not for commercial exploitation.

- Capacity-building, legal aid and culturally appropriate IP education

Training should be provided to indigenous communities on IP, contract negotiation, data management and commercialization strategies to empower them in protecting and managing their traditional knowledge and genetic resources. Such training should enhance community awareness of their legal rights, equip them to engage effectively with external researchers or corporations, and support informed decision-making in access and benefit-sharing (ABS) negotiations.

- **Fund capacity building**

A dedicated legal aid mechanisms to assist communities in pursuing legal remedies, negotiating fair benefit-sharing agreements and enforcing their rights under national and international frameworks. Easy Access to professional legal and technical expertise ensures that communities are not disadvantaged in complex negotiations, thereby promoting equity, transparency, and sustainable partnerships between traditional knowledge holders and commercial entities.

- **Corporate due diligence and supply-chain transparency**

Mandate corporate disclosure of any use of genetic resources and traditional knowledge (TK) within their value chains, ensuring transparency and accountability in sourcing and innovation processes. Companies should be required to demonstrate compliance with Access and Benefit-Sharing (ABS) obligations and adherence to community protocols governing the use of such resources as a condition for obtaining licenses, permits, or procurement approvals.

This disclosure requirement should be integrated into corporate due diligence frameworks, compelling businesses to trace the origin of genetic materials and TK, document consent and benefit-sharing arrangements, and publicly report on compliance. Embedding these obligations into national licensing and procurement systems promotes ethical supply chains, prevents biopiracy, and aligns corporate practices with the principles of fairness, equity, and sustainability under international instruments such as the Nagoya Protocol.

- Multi-stakeholder governance and dispute-resolution mechanisms

Establish accessible and culturally sensitive dispute resolution mechanisms to address conflicts related to Traditional Knowledge (TK) and Intellectual Property (IP) rights. These mechanisms should include community-based tribunals and hybrid arbitration models that blend customary laws and traditional practices with formal legal principles, ensuring that dispute resolution reflects the cultural values and governance systems of indigenous and local communities.

Additionally, create national ombudspersons or dedicated grievance office for TK/IP claims to provide neutral, low-cost, and efficient avenues for resolving disputes, mediating benefit-sharing disagreements, and addressing cases of misappropriation. Such institutions can also monitor compliance with Access and Benefit-Sharing (ABS) laws and safeguard community rights.

By integrating customary justice systems with national legal frameworks, these approaches promote fairness, trust, and inclusivity, ensuring that indigenous voices are respected and that remedies are both legally sound and culturally legitimate.

- Implement Nagoya Protocol obligations effectively-

Nagoya Protocol should be implemented effectively by enacting clear and comprehensive Access and Benefit-Sharing (ABS) laws that define the rights and responsibilities of all stakeholders. These laws should establish transparent, accessible, and user-friendly procedures for indigenous and local communities to negotiate Mutually Agreed Terms (MAT) for access to genetic resources and associated traditional knowledge.

Such frameworks should include guidance on obtaining Free, Prior, and Informed Consent (FPIC), mechanisms for fair benefit-sharing, and monitoring systems to ensure compliance. By providing communities with clear legal pathways and procedural support, states can

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facilitate equitable partnerships, prevent misappropriation, and uphold both national interests and international obligations under the Nagoya Protocol.

- **Training to patent examiners**

Train patent examiners to recognize Traditional Knowledge (TK) and Traditional Cultural Expressions (TCEs) by providing specialized education on the characteristics, sources, and cultural significance of such knowledge. This training should cover how TK and TCEs differ from conventional inventions, their collective and intergenerational nature, and the legal and ethical considerations involved in their use.

Examiners should also be trained to effectively utilize TK documentation, such as defensive databases (e.g., TKDL), as part of prior art searches to ensure that patent applications do not improperly claim knowledge that already exists within communities. This includes understanding how to interpret community protocols, cross-reference documented TK, and apply it accurately in the patent examination process.

- **Assist countries and communities in establishing <sup>\*\*</sup>Traditional Knowledge (TK) documentation projects-**

Communities should be empowered to govern how their knowledge is recorded, accessed, and shared, including setting rules for third-party use, benefit-sharing, and consent procedures. Technical assistance may cover digital infrastructure, metadata standards, and security measures, while legal support ensures binding agreements and protective protocols are in place.

## **Conclusion**

The protection and equitable commercialization of Traditional Knowledge demand a sustained, multi-level effort. In the short term, priority must be given to strengthening defensive mechanisms like the TKDL and enforcing disclosure requirements in patent law. Pilot ABS agreements can build trust and model best practices. In the medium term, the enactment of robust sui generis laws and the establishment of transparent benefit-sharing funds are critical. Long-term success depends on the harmonization of national regimes with evolving international law, the embedding of ethical due diligence into corporate governance, and, most importantly, the empowerment of Indigenous communities through capacity building and genuine participation in governance.

India's experience demonstrates that a hybrid approach—blending technological innovation like the TKDL with ongoing democratic debate and incremental legal reform—provides a valuable model. It shows that safeguarding TK is not merely a legal technicality but a complex endeavor requiring political will, institutional creativity, and unwavering respect for the rights and wisdom of Indigenous and local communities. The ultimate goal is a global ecosystem where innovation is inclusive, and traditional knowledge holders are recognized as equal partners and equitably rewarded for their invaluable contributions to humanity's shared heritage and future.

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