

## Research Article

# Traditional Knowledge in Drug Development and the Rights of Indigenous Peoples: A Legal and Ethical Perspective

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### Abstract

This paper delves into the intersection of traditional knowledge and drug development, highlighting the critical contributions of indigenous wisdom to pharmaceutical advancements while examining the associated legal and ethical challenges. Traditional knowledge, encompassing centuries of indigenous expertise in medicinal plants and natural remedies, has been instrumental in the discovery of significant drugs, such as aspirin derived from willow bark. Despite the growing global interest in natural products and traditional medicine, indigenous communities face significant challenges in protecting their knowledge and securing their rights against exploitation and biopiracy. The paper critically evaluates the inadequacies of existing Intellectual Property Rights (IPR) frameworks in safeguarding traditional knowledge, addressing the complexities inherent in applying patent laws to such knowledge. It explores relevant international treaties, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access and Benefit-sharing (ABS), which aim to regulate access and ensure fair compensation for indigenous communities. Furthermore, it examines national legal frameworks in countries like India, Brazil, and Peru, assessing their effectiveness in promoting fair benefit-sharing and protecting indigenous rights. In addition, the paper addresses ethical and legal challenges related to biopiracy and the necessity of obtaining Free, Prior, and Informed Consent (FPIC) from indigenous communities. Through detailed case studies, it highlights both successful and unsuccessful efforts to integrate traditional knowledge into drug development, offering valuable lessons and best practices. The paper concludes with policy recommendations aimed at reforming IPR laws, enhancing international and national mechanisms, and promoting equitable benefit-sharing to ensure that traditional knowledge is utilized responsibly, fairly, and sustainably.

**Keywords:** Traditional knowledge; Drug development; Indigenous communities; Rights of indigenous peoples; Case studies

### Introduction

Traditional knowledge is a vital component in drug

development, offering a wealth of medicinal information preserved within indigenous communities over generations. This knowledge, which includes the use of plants, minerals, and natural compounds for healing, is often rooted in centuries of empirical evidence. In recent decades, the pharmaceutical industry has increasingly recognized its value, especially in the domains of herbal medicine and natural product pharmacology.

In the Indian context, the Constitution broadly recognizes social and economic justice, emphasizing the welfare of all citizens. The terms 'social justice' and 'welfare' are mentioned used 4 times and 29 times, within the constitutional text, reflecting the nation's commitment to achieving equity and improving the well-being of its people [1]. By promoting the use of traditional knowledge in areas like healthcare, India advances its constitutional goals of fostering both social justice and welfare.

Traditional knowledge has played a crucial role in drug development, contributing significantly to the discovery of many modern medicines [2]. This knowledge, accumulated by indigenous communities over centuries, includes the use of medicinal plants, herbs, and natural remedies [3]. Notable examples include quinine from the cinchona tree used by South American indigenous people to treat fevers, which became a major antimalarial drug; aspirin, derived from the ancient use of willow bark for pain relief; artemisinin from *Artemisia annua* in Chinese traditional medicine, now a cornerstone in malaria treatment; and the rosy periwinkle

from Madagascar, leading to the development of cancer-treating drugs like vinblastine and vincristine [4-7]. These cases highlight traditional knowledge as a foundation for modern pharmaceuticals but also raise critical issues regarding the recognition of indigenous rights, fair compensation, and the ethical use of this knowledge [8].

The increasing global interest in traditional medicine and natural products reflects a shift towards holistic health practices, sustainability, and ethical considerations. Traditional medicine emphasizes whole-body health and prevention, resonating with those seeking alternatives to symptom-focused Western medicine. Systems like Ayurveda, Traditional Chinese Medicine, and other indigenous practices offer remedies often associated with fewer side effects than synthetic pharmaceuticals. Moreover, traditional medicine integrates mental, spiritual, and physical well-being, aligning with modern patients' values and the growing concern for natural health solutions [9-12].

Natural products have been a cornerstone of pharmaceutical innovation, with over half of all drugs either derived from or inspired by natural sources. Traditional knowledge guides researchers to bioactive substances, transforming them into modern medicine [13,14]. For instance, the knowledge of the medicinal properties of plants like *Artemisia annua* facilitated the discovery of artemisinin, now a key malaria treatment [15]. However, this exploration brings complex legal questions about ownership of traditional knowledge and equitable benefit-sharing.

In recent years, antimicrobial resistance has spurred an intensified search for new agents, focusing on traditional medicinal plants known for their infection-fighting properties. Here, indigenous botanical knowledge becomes invaluable. Yet, the commercial exploration of these plants raises ethical and legal issues. It is crucial to develop legal frameworks that ensure the extraction and use of such knowledge do not exploit indigenous communities [16].

Another driver of global interest in traditional medicine is the focus on sustainability and biodiversity. Traditional medicine often relies on locally available, renewable resources, promoting a sustainable approach to health [17]. This aligns with global efforts to protect ecosystems and combat climate change. The traditional use of plants for medicine has legal implications for protecting indigenous lands and knowledge. Therefore, the law must harmonize environmental, intellectual property, and human rights laws to safeguard ecosystems and community rights.

The economic dimension of traditional medicine is significant, especially in developing countries where it forms the primary healthcare resource [18]. The global market for traditional medicinal products and supplements has grown into a multi-billion-dollar industry, intensifying the need to protect indigenous knowledge through fair compensation and benefit-sharing [19]. Current Intellectual Property Rights (IPR) frameworks often clash with the communal nature of traditional knowledge. This

misalignment has resulted in biopiracy, where companies patent indigenous plants without proper consent or sharing benefits with the originating communities. Addressing these challenges requires a nuanced understanding of IPRs, traditional knowledge databases, and treaties like the Nagoya Protocol.

Integrating traditional medicine into modern healthcare systems amplifies the need for legal protections [20]. Governments are incorporating traditional medicine into health policies, providing it with legal recognition and promoting cross-disciplinary research. However, this integration poses critical legal questions concerning intellectual property protections and the recognition of indigenous knowledge, which is often communal and intergenerational. Hence, an evolved legal framework is needed to accommodate the unique characteristics of traditional knowledge and ensure that knowledge holders are appropriately recognized and compensated.

Despite the promise of traditional knowledge in drug development, indigenous communities face challenges in protecting their knowledge, particularly within global pharmaceutical and intellectual property regimes [21]. Current IPR systems, designed to protect individual and corporate inventions, do not suit the collective, orally transmitted, and evolving nature of traditional knowledge. Consequently, indigenous communities struggle to claim ownership or receive compensation under conventional IPR laws. This misalignment has led to biopiracy, where corporations exploit traditional knowledge without acknowledgment or benefit-sharing.

Biopiracy illustrates the exploitation of indigenous knowledge, with companies patenting plants like neem and turmeric without consent. Despite international outcry, indigenous communities often lack the legal capacity to challenge such patents [22]. This exploitation not only infringes on their rights but also undermines their cultural heritage and autonomy. International agreements, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, seek to establish frameworks for access and benefit-sharing (ABS). However, these mechanisms are difficult for indigenous communities to navigate, often due to lack of legal expertise and representation. Moreover, benefit-sharing agreements often inadequately compensate these communities for the commercial use of their knowledge and resources.

The principle of Free, Prior, and Informed Consent (FPIC) is vital to protecting indigenous rights [23]. However, it is frequently ignored when traditional knowledge is exploited. Indigenous communities often face pressure to consent to the use of their knowledge without being fully informed of the implications, violating their sovereignty. The commercialization of traditional knowledge can also erode cultural practices, stripping them of their spiritual and cultural significance. This issue is compounded by economic pressures that force communities to alter traditional practices to suit market demands, undermining cultural integrity.

Power imbalances between indigenous communities and corporations exacerbate these challenges. Corporations have the legal and financial resources to secure patents, while indigenous communities often lack access to legal support. This imbalance results in agreements favouring commercial entities and limiting indigenous communities' ability to assert their rights or benefit meaningfully from commercialization [24].

Although some countries have introduced policies to protect traditional knowledge, effectiveness varies. Often, these laws lack clarity, consistency, and enforcement mechanisms. Addressing these challenges requires reforming intellectual property regimes to recognize communal rights and establishing mechanisms for equitable benefit-sharing and consent.

The intersection of traditional knowledge and drug development raises pressing legal and ethical questions, especially concerning indigenous rights. Indigenous communities have been custodians of traditional knowledge for generations, providing the basis for numerous modern drugs. However, the pharmaceutical industry's use of this knowledge often occurs without adequate recognition or compensation.

In India, the Forest Rights Act of 2006 acknowledges the historical injustices faced by forest-dwelling communities, granting them rights to manage forest resources [25]. However, the application of such laws in the context of bioprospecting for drug development remains a challenge. The current intellectual property frameworks often fail to recognize communal ownership of knowledge. Benefit-sharing mechanisms, as promoted by international agreements like the CBD and the Nagoya Protocol, aim to ensure fair compensation, but their implementation is fraught with issues related to power imbalances and lack of participation by indigenous communities.

This paper argues for legal solutions that not only facilitate the development of life-saving drugs but also uphold the rights and dignity of indigenous peoples. It calls for a re-evaluation of intellectual property laws to better accommodate traditional knowledge and ensure fair benefit-sharing. Proper legal frameworks and policies must recognize indigenous communities as rightful knowledge holders and ensure that their contributions are utilized responsibly, fairly, and sustainably.

### **Traditional knowledge and its contribution to drug development**

**Definition and scope:** Traditional knowledge embodies the collective wisdom, practices, and innovations developed and passed down through generations within indigenous communities. It is interwoven with the cultural, spiritual, and environmental relationship of these communities with their surroundings. This dynamic knowledge system covers a wide range of information, including medicinal plant use, agricultural practices, spiritual rituals, environmental management, and oral histories [26]. Unlike Western scientific knowledge, traditional knowledge is primarily

transmitted orally and evolves to adapt to changing social and environmental circumstances [27].

**Scope of traditional knowledge includes: Medicinal knowledge:** Indigenous communities possess a profound understanding of natural resources for health and healing. They use plants, minerals, and natural substances to treat various ailments, employing detailed knowledge of the properties, preparation methods, and therapeutic effects of these substances. This knowledge has informed modern pharmacology, with medicines such as quinine, artemisinin, and vincristine originating from traditional practices. Traditional medicinal knowledge includes the overall practices of healthcare and wellness, emphasizing a holistic understanding of the human body's relation to nature [28].

**Environmental and ecological knowledge:** Indigenous knowledge includes sophisticated insights into local ecosystems, biodiversity, and resource management. Communities employ techniques for sustainable agriculture, forest management, water conservation, and wildlife utilization while maintaining ecological balance. Their stewardship of biodiversity, understanding of plant species, soil conditions, and climate patterns, greatly aids in conservation efforts and sustainable development [29].

**Cultural and spiritual practices:** Traditional knowledge is deeply rooted in cultural and spiritual practices, reflecting a worldview of interconnectedness between humans, nature, and the cosmos. Rituals, customs, and storytelling preserve and convey this knowledge, often providing ethical guidelines for environmental interaction. The spiritual dimension includes knowledge of sacred sites, rituals for harvesting plants, and ceremonies promoting ecological harmony, adding layers of meaning beyond mere utilitarian use [30].

**Agricultural practices:** Indigenous knowledge extends to agriculture, encompassing seed selection, crop rotation, soil fertility management, and pest control. This wisdom has helped communities develop resilient food systems adapted to local conditions, contributing to food security. Traditional knowledge also informs food preservation and processing, including the use of medicinal plants as dietary supplements [31].

**Unique characteristics of traditional knowledge:** Traditional knowledge differs from scientific knowledge in its communal nature, oral transmission, and adaptive quality. It is collectively held by the community and transmitted through traditions, rituals, apprenticeships, and practices. It evolves with experience and environmental interaction, responding to new challenges and integrating external influences [32].

### **Traditional knowledge in pharmacology**

**Botanical knowledge:** Indigenous communities possess detailed botanical knowledge for identifying, collecting, preparing, and using plants therapeutically. This includes classifying plants based on observable traits and understanding optimal growth conditions.

Preparation methods are crucial, involving techniques like drying, grinding, boiling, or combining plant parts [33]. For example, Ayurvedic medicine requires meticulous processes such as decoction and fermentation.

**Ethnopharmacology and holistic healing:** Indigenous healing practices involve a holistic approach, combining herbal medicine, spiritual rituals, dietary guidelines, and lifestyle adjustments [34]. Traditional medicine often employs synergistic use of multiple herbs to address the root causes of ailments. Spiritual elements, such as the use of sacred plants in rituals, reflect the integration of physical, mental, and spiritual well-being.

**Knowledge of biodiversity and conservation:** Traditional pharmacological knowledge is linked to ecological wisdom, emphasizing sustainable harvesting, rotational gathering, and ceremonial offerings [35]. Indigenous communities practice cultivation of medicinal plants within agroforestry systems, which supports biodiversity and ecological resilience. Their understanding of soil types, climate, and plant cycles offers valuable insights for sustainable agriculture.

**Toxicology and safety:** Indigenous pharmacological knowledge includes the understanding of toxicity, dosage, and safety measures [36]. Healers are aware of which plants can be toxic, the conditions that may enhance toxicity, and how to neutralize harmful effects. For example, some communities use specific clay types to detoxify plants before consumption, demonstrating a nuanced understanding of plant chemistry.

**Historical context:** Traditional knowledge and significant drug discoveries: The relationship between traditional knowledge and pharmaceutical development is a significant historical intersection, showcasing how indigenous wisdom has influenced modern medicine. This synergy between ancient practices and contemporary drug discovery is evident in several key examples.

**Willow bark and aspirin:** Willow bark's use for pain relief dates back to ancient civilizations like the Sumerians, Greeks, and Native Americans, who employed it for headaches, fever, and pain [37]. The bark contains salicin, which was later analyzed in the 19th century, leading to the synthesis of acetylsalicylic acid (aspirin) by Bayer in 1899. This synthetic version was more effective and gentler on

the stomach, revolutionizing pain management. Aspirin's development illustrates how empirical knowledge of natural remedies can drive pharmaceutical advancements [38].

**Quinine and malaria treatment:** Indigenous peoples in South America used the Cinchona tree's bark to treat malaria, a remedy discovered by Spanish colonizers in the 17th century [39]. Quinine, the active compound, was isolated in the early 19th century and confirmed as an effective antimalarial. This treatment saved countless lives and set the foundation for the development of other antimalarial drugs, highlighting traditional knowledge's crucial role in global health [40].

**Artemisinin and malaria treatment:** Traditional Chinese medicine has used *Artemisia annua* (sweet wormwood) for centuries to treat fevers. In the 1970s, Chinese scientist Tu Youyou, inspired by ancient texts, isolated artemisinin as a potent malaria treatment [41]. Artemisinin-based Combination Therapies (ACTs) are now the standard treatment for malaria, especially in areas with drug-resistant strains. Tu Youyou's work exemplifies how traditional knowledge can lead to groundbreaking medical advancements [42].

**Vincristine and cancer treatment:** The rosy periwinkle (*Catharanthus roseus*), native to Madagascar, was used by indigenous Malagasy communities for its medicinal properties. In the 1950s, scientists isolated vincristine from the plant, leading to its use in treating cancers like leukemia and lymphoma. This discovery underscores the potential of traditional herbal knowledge in developing effective cancer treatments [43].

**Digitalis and heart disease:** *Digitalis purpurea* (foxglove) was traditionally used in European herbal medicine for heart ailments. In the early 19th century, the compound digoxin was isolated and scientifically validated for its cardiotonic effects [44]. This transition from traditional remedies to modern pharmaceuticals provided a cornerstone for treating heart failure and arrhythmias, demonstrating how botanical knowledge can be integrated into contemporary medicine [45].

These examples underscore the importance of traditional knowledge in drug discovery and the potential benefits of preserving indigenous practices (Table 1).

**Table 1:** Challenges and opportunities in integrating traditional knowledge into modern drug discovery and development

S No.	Challenges	Opportunities
1	Intellectual Property Rights (IPR): Protecting traditional knowledge within existing IPR frameworks is complex, as traditional remedies are often considered part of the public domain. Patent systems typically do not account for communal ownership or knowledge passed down through generations	Novel drug discovery: Traditional knowledge provides a rich source of information about potential medicinal plants and natural compounds that can lead to the discovery of novel drugs and therapies
2	Biopiracy and misappropriation: Instances of biopiracy occur when companies patent compounds or products derived from traditional knowledge without the consent of indigenous communities, leading to exploitation and loss of cultural heritage	Sustainable resource use: Collaborations with indigenous communities can promote the sustainable use of medicinal plants and biodiversity conservation, fostering ecological balance
3	Benefit-sharing issues: There is often a lack of fair and equitable benefit-sharing mechanisms for indigenous communities who contribute their traditional knowledge to drug development. This leads to economic and ethical concern	Collaborative research: Integrating traditional knowledge with modern scientific research provides opportunities for collaborative studies that can validate traditional medicine's efficacy and safety

4	Knowledge erosion: As globalization and modernization progress, traditional knowledge is at risk of being lost. Younger generations in indigenous communities may be less inclined to learn and preserve traditional medicinal practices	Enhancing drug efficacy: Insights from traditional medicine can guide the identification of active compounds, potentially leading to the development of more effective, multi-target pharmaceuticals
5	Lack of standardization: Traditional remedies often lack the standardized dosage and formulation required for modern drug development, making it challenging to conduct clinical trials and gain regulatory approval	Cost-effective research: Traditional knowledge can streamline the drug discovery process by offering preliminary evidence of efficacy, reducing the time and cost associated with exploratory research
6	Ethical and cultural sensitivity: Integrating traditional knowledge into modern medicine must be approached with cultural sensitivity, respecting indigenous practices, beliefs, and the spiritual significance of medicinal plants	Strengthening indigenous rights: Formal recognition of traditional knowledge in drug development can empower indigenous communities, advocating for their rights and preserving cultural heritage
7	Regulatory hurdles: Modern drug development involves stringent regulatory requirements. Traditional knowledge often lacks the scientific documentation required for regulatory approval, posing a barrier to commercialization	Diversifying the drug portfolio: Traditional knowledge offers a diverse range of medicinal plants and natural remedies that can enrich the global pharmaceutical portfolio, particularly in the area of natural products
8	Mistrust between communities and corporations: Historical instances of exploitation have created mistrust between indigenous communities and pharmaceutical companies, potentially hindering collaboration	Intellectual exchange: Collaboration between traditional healers and scientists can lead to knowledge exchange, fostering innovations that blend traditional wisdom with scientific rigor

## Research Methodology

This research employs a doctrinal legal methodology, focusing on analyzing legal principles, statutes, and scholarly commentary to explore the integration of traditional knowledge in drug discovery and the rights of indigenous communities. It adopts a case study approach, examining specific instances such as *Hoodia gordonii*, neem, and turmeric, where traditional knowledge has contributed to pharmaceutical innovations or sparked legal disputes over Intellectual Property Rights (IPR) and benefit-sharing. The study involves interpreting key statutes like the Forest Rights Act, 2006, and the Biological Diversity Act, 2002, alongside international treaties such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol. Through in-depth analysis of case studies and statutory frameworks, the research aims to identify legal gaps and challenges in protecting traditional knowledge and securing the rights of indigenous people. By exploring these case studies, it seeks to highlight the complexities of IPR, the effectiveness of current legal mechanisms, and the need for equitable benefit-sharing, providing a foundation for recommendations to improve traditional knowledge protection within the pharmaceutical industry.

## Legal frameworks and indigenous rights

### Forest Rights Act (FRA) and traditional knowledge:

The existing framework of the Forest Rights Act (FRA) of 2006, while a landmark piece of legislation in recognizing the rights of forest-dwelling communities in India, is fundamentally inadequate in addressing the complexities involved in the protection of traditional knowledge. One of the primary inadequacies lies in the Act's limited scope and focus on land and forest rights rather than directly addressing the intellectual property and benefit-sharing aspects associated with the indigenous knowledge of medicinal plants, herbs, and other forest resources. Although the FRA recognizes the community's right to manage, protect, and conserve forest resources, it does not extend to providing robust mechanisms for safeguarding the traditional knowledge derived from those resources, leaving indigenous communities vulnerable to biopiracy

and exploitation by commercial entities.

Furthermore, the FRA does not establish a concrete legal framework for Intellectual Property Rights (IPR) that could shield traditional knowledge from unauthorized use or patent claims by external actors. As a result, multinational corporations can extract valuable traditional knowledge, often without adequate consent or compensation, because the current FRA framework does not explicitly confer ownership or provide enforceable rights over traditional medicinal practices, plant uses, or associated knowledge. Additionally, the benefit-sharing mechanisms under the FRA remain ambiguous and insufficient, particularly when juxtaposed with international obligations under instruments like the Nagoya Protocol, which mandate fair and equitable sharing of benefits arising from the use of genetic resources. This lack of specificity in the FRA places indigenous communities in a precarious position, as they often lack the legal resources or awareness to navigate complex IPR laws and negotiate equitable benefit-sharing agreements.

The FRA's procedural provisions for recognizing community rights also pose significant challenges. For example, the requirement of evidence for claiming rights, such as documentation of historical use, places an undue burden on indigenous communities, whose traditional knowledge is typically oral and transmitted through generations. The Act's failure to consider the oral nature of such knowledge exacerbates the difficulty of securing protection, as indigenous communities may be disqualified from claiming ownership over their traditional practices. This oversight reflects a larger systemic issue: the FRA's orientation towards land and resource rights fails to capture the intangible yet invaluable nature of traditional knowledge. Consequently, the current FRA framework, while a progressive step toward recognizing indigenous rights, remains fundamentally inadequate in providing a holistic legal mechanism that not only acknowledges but actively protects traditional knowledge in the face of global commercial interests.

Applying patent laws to traditional knowledge, particularly

within the context of the Forest Rights Act (FRA) of 2006, presents significant legal and practical complexities. Patent law traditionally favors novel, inventive, and industrially applicable innovations, which directly conflicts with the nature of traditional knowledge that has been practiced, refined, and passed down through generations within indigenous communities. Under the FRA, indigenous communities have rights over their forest resources, but the Act does not provide an explicit legal framework for the protection of traditional knowledge related to these resources. This absence leaves traditional knowledge vulnerable to misappropriation, as patent systems are ill-equipped to recognize and protect knowledge that does not fit within the rigid criteria of novelty and inventiveness.

One of the primary complexities in applying patent laws to traditional knowledge is the issue of “prior art.” Traditional knowledge often lacks formal documentation and has not been publicly disclosed in a manner recognized by patent offices. This oral and community-held knowledge, despite being ancient, may not meet the legal requirements for proving prior art, allowing third parties to claim patents on derivatives of this knowledge. For example, even though indigenous communities have long used certain plant species for medicinal purposes, the lack of formal documentation often enables corporations to patent these uses or derivatives without acknowledging the original holders of the knowledge. This situation leads to “biopiracy,” where corporations profit from traditional knowledge while indigenous communities are denied recognition and benefit-sharing.

Furthermore, patent law’s focus on individual ownership conflicts with the collective nature of traditional knowledge. Indigenous knowledge is typically held communally, with practices and uses governed by cultural norms rather than individual claims. Patent systems, however, require a specific inventor or entity to be named, thereby sidelining the collective ownership model that is intrinsic to many indigenous communities. The FRA does recognize collective rights to forest resources, but it does not extend these rights to encompass traditional knowledge in a way that aligns with the requirements of patent law. This gap leaves indigenous communities in a legally precarious position, where their traditional knowledge can be appropriated by others without adequate legal recourse.

Moreover, the complexities of the benefit-sharing arrangements under the FRA intersect problematically with the application of patent laws. The FRA mentions the rights of communities to access, use, and conserve forest resources, yet it does not articulate a clear mechanism for ensuring that communities receive a fair share of benefits derived from the commercialization of their traditional knowledge. International agreements like the Nagoya Protocol provide a more robust framework for equitable benefit-sharing, but integrating these principles within the patent system remains difficult, as it requires balancing intellectual property rights with the community-based nature of traditional knowledge.

### **Intellectual property rights and traditional knowledge:**

The existing Intellectual Property Rights (IPR) frameworks, primarily designed to protect novel and individual inventions, are woefully inadequate for safeguarding traditional knowledge [46]. These frameworks, including patent law, copyright, and trademark regimes, are fundamentally structured around the notions of originality, innovation, and individual ownership—principles that starkly contrast with the communal, collective, and intergenerational nature of traditional knowledge held by indigenous communities. Consequently, traditional knowledge often falls outside the purview of conventional IPR protections, leaving it vulnerable to misappropriation and exploitation.

Firstly, patent law demands that an invention be novel, non-obvious, and have industrial applicability [47]. However, traditional knowledge often does not meet these stringent criteria [48]. For instance, many traditional medicinal practices are based on centuries-old empirical use of natural resources, knowledge that has been refined through communal experience rather than an identifiable, singular act of innovation. In this context, TK is considered part of the public domain, making it ineligible for patent protection. This loophole allows external entities, particularly pharmaceutical companies, to appropriate traditional knowledge, patent its isolated components, and profit without recognizing or compensating the indigenous communities that cultivated this knowledge. The patenting of neem extracts, turmeric, and other traditional remedies illustrates this critical flaw, where patents were initially granted to those who “discovered” the use of these plants despite their long-standing traditional applications.

Secondly, traditional knowledge is inherently communal and passed down through generations [49]. It does not belong to a single individual or entity but rather to a community that serves as its custodian. Existing IPR frameworks, however, revolve around the concept of exclusive rights granted to a defined owner or inventor [50]. This individualistic approach fails to account for the collective nature of TK ownership, creating a significant barrier for indigenous communities seeking to assert their rights. Additionally, IPR protections are time-bound; patents, for example, typically last for 20 years. In contrast, traditional knowledge does not have an expiration date; it is continuously evolving and adapting, often over centuries. The temporally limited nature of patent rights is incompatible with the perpetual nature of traditional knowledge, further underscoring the inadequacy of these frameworks.

Moreover, the current IPR system does not adequately address the issue of benefit-sharing, a cornerstone of ethical considerations in the use of traditional knowledge. International instruments like the Convention on Biological Diversity (CBD) and the Nagoya Protocol call for fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge. However, these guidelines have yet to be fully integrated

into national IPR systems. Even when some benefit-sharing agreements are made, they often fall short in practice due to power imbalances, lack of legal literacy among indigenous communities, and insufficient mechanisms to enforce equitable sharing.

The inadequacies of existing IPR frameworks in protecting traditional knowledge highlight an urgent need for reform. Possible solutions include developing *sui generis* (unique) legal systems tailored specifically to recognize the communal nature of TK, ensuring perpetual protection, and establishing mechanisms for mandatory benefit-sharing. Additionally, the establishment of traditional knowledge databases could play a vital role in preventing biopiracy by providing evidence of prior use, thereby disqualifying the grant of patents on knowledge already known to indigenous communities. Addressing these gaps in the IPR regime is imperative to respecting the rights of indigenous peoples, promoting equity in benefit-sharing, and preserving the invaluable heritage of traditional knowledge.

Applying patent laws to Traditional Knowledge (TK) is fraught with complexities due to the fundamental differences between the nature of TK and the underlying principles of patent law. Patent systems are designed to protect novel, non-obvious inventions that have industrial applicability and are typically created by identifiable inventors. In contrast, traditional knowledge encompasses long-standing cultural practices, ecological wisdom, and medicinal know-how that have evolved collectively over generations within indigenous communities. This discord between the collective, ancient nature of TK and the individualized, innovation-centric focus of patent laws creates multiple legal and ethical challenges.

One of the primary complexities lies in the requirement of novelty. Patent law mandates that an invention must be new and not previously known to the public [51]. However, traditional knowledge is often rooted in ancient practices, passed down through oral traditions, and widely known within the indigenous communities [52]. This common use and lack of “newness” make it virtually impossible for TK to meet the novelty criterion of patent law. When traditional knowledge is used to develop a new pharmaceutical product, the raw knowledge itself—such as the medicinal properties of a particular plant—does not qualify for patent protection because it is pre-existing. This allows external entities to isolate active compounds from plants used in traditional medicine, modify them slightly, and patent these derivatives without recognizing the underlying TK.

Furthermore, patent laws require non-obviousness, meaning the invention must not be obvious to someone with ordinary skill in the field. In traditional knowledge systems, the value lies in the cumulative knowledge of natural resources and their applications, which may seem “obvious” to those practicing traditional medicine. This creates an inherent bias in the patent system, as it does not account for the complexity and empirical research that indigenous communities have undertaken over centuries. As a result, companies can exploit TK by making minor

modifications to known natural remedies, thus meeting the non-obviousness requirement in the eyes of patent law while disregarding the sophisticated knowledge systems that identified the remedy in the first place.

Another critical issue is the identification of inventorship and ownership. Patent law is based on the idea that an individual or a defined group of inventors creates a novel invention. However, traditional knowledge is typically owned collectively by the community and not attributed to specific individuals. This communal ownership makes it exceedingly difficult to satisfy the legal requirement of identifying a specific inventor for patent purposes. Additionally, indigenous communities often lack formalized documentation of their knowledge, as it is traditionally transmitted orally. Without documented evidence, it becomes challenging to assert ownership or establish prior use, creating a loophole that can be exploited by those seeking to patent traditional knowledge or its derivatives.

The temporal limitation of patent protection also conflicts with the nature of traditional knowledge. Patent rights are granted for a limited duration, usually 20 years, after which the patented invention falls into the public domain. In contrast, traditional knowledge is perpetually relevant and adaptable, passed through generations and continuously evolving. Therefore, applying a time-bound legal framework to TK is incompatible with the ongoing nature of indigenous practices and wisdom.

The scope of patentable subject matter further complicates the application of patent laws to TK. Many traditional remedies involve natural processes, plant extracts, or simple methods of preparation, which often do not meet the criteria for patentable subject matter, especially in jurisdictions that exclude natural phenomena or traditional practices from patent eligibility. However, this exclusion can be circumvented by external actors who isolate and modify specific compounds from plants used in traditional medicine, thereby creating a “patentable” product based on traditional knowledge.

Benefit-sharing is another layer of complexity. International treaties, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, advocate for fair and equitable sharing of benefits arising from the utilization of traditional knowledge. However, existing patent laws do not adequately incorporate these benefit-sharing principles, leading to situations where indigenous communities do not receive appropriate recognition or compensation when their knowledge is commercialized.

These complexities underscore the need for legal reforms that better align patent laws with the characteristics of traditional knowledge. Possible solutions include the development of *sui generis* legal systems that recognize the collective nature of TK, promote perpetual protection, and incorporate equitable benefit-sharing mechanisms. Additionally, traditional knowledge databases could serve as a means to document and provide evidence of prior use, preventing the misappropriation and unauthorized

patenting of traditional knowledge. Addressing these legal complexities is essential to ensure that patent laws serve not only the interests of innovation but also the rights and cultural heritage of indigenous communities.

### **International treaties and indigenous rights to traditional knowledge**

The Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access and Benefit-sharing represent crucial milestones in the international recognition of the rights of indigenous peoples to their traditional knowledge, particularly in relation to biodiversity and the use of natural resources. These treaties, while not without their implementation challenges, have laid a foundational legal framework that acknowledges the invaluable contributions of indigenous knowledge to biodiversity conservation, sustainable use, and the development of pharmaceuticals.

The Convention on Biological Diversity (CBD), adopted in 1992, was one of the first international agreements to formally recognize the role of indigenous and local communities in conserving biological diversity [53]. Notably, Article 8(j) of the CBD explicitly calls on signatory states to respect, preserve, and maintain the traditional knowledge, innovations, and practices of indigenous and local communities that are relevant for the conservation and sustainable use of biological diversity [54]. It further mandates that states promote the wider application of such knowledge, provided that it occurs with the approval and involvement of the knowledge-holding communities. This clause acknowledges the collective nature of traditional knowledge and the critical need for consent and involvement from indigenous peoples in decisions that affect their knowledge systems.

However, the CBD's significance goes beyond merely recognizing traditional knowledge; it also introduces the principles of Access and Benefit-Sharing [55]. These principles aim to ensure that when genetic resources and associated traditional knowledge are accessed for research and commercial use, indigenous communities are entitled to a fair and equitable share of the benefits that arise from such utilization. This was a substantial shift in international law, moving away from the previous norms that allowed free access to genetic resources without consideration for the rights of the original knowledge holders. However, while the CBD set forth these ground breaking principles, its provisions lacked specificity, leading to the development of the Nagoya Protocol to provide a more detailed legal mechanism for implementation.

The Nagoya Protocol on Access and Benefit-sharing, adopted in 2010, serves as a supplementary agreement to the CBD, providing a comprehensive framework for the implementation of the CBD's ABS principles [56]. One of the key aspects of the Nagoya Protocol is its emphasis on prior informed consent and mutually agreed terms when accessing genetic resources and associated traditional knowledge [57,58]. This requirement ensures that indigenous communities are actively involved in

negotiations and that their consent is obtained before their knowledge or resources are utilized. Additionally, the Nagoya Protocol stresses the need for benefit-sharing to be fair and equitable, encompassing both monetary benefits (such as royalties and licensing fees) and non-monetary benefits (such as technology transfer, capacity building, and research collaboration). This holistic approach to benefit-sharing aims to address power imbalances and ensure that indigenous communities receive meaningful compensation for the use of their knowledge and resources.

Furthermore, the Nagoya Protocol acknowledges the customary laws and practices of indigenous and local communities, reinforcing the need for any access to traditional knowledge to align with these communities' norms [59]. This recognition serves as a critical safeguard, emphasizing that benefit-sharing must respect not only the knowledge itself but also the cultural and spiritual values embedded within it. The protocol also encourages the development of community protocols and traditional knowledge databases to aid in the documentation, protection, and management of indigenous knowledge systems.

Despite their progressive nature, both the CBD and the Nagoya Protocol face significant implementation challenges [60]. States are responsible for enacting domestic legislation to comply with these international treaties, and the degree of implementation varies widely. Some countries have developed detailed ABS frameworks and benefit-sharing regulations, while others have struggled with enforcement, especially in cases involving multinational corporations and cross-border access to traditional knowledge. Moreover, the effectiveness of these treaties often hinges on the capacity of indigenous communities to navigate complex legal and administrative processes, which can be a daunting task given historical marginalization, limited legal literacy, and resource constraints.

Additionally, while the Nagoya Protocol provides mechanisms for benefit-sharing, it does not directly address Intellectual Property Rights (IPR) issues, leaving a gap in how patents based on traditional knowledge are managed. This oversight can lead to situations where traditional knowledge is patented without proper recognition or benefit-sharing, highlighting a need for more robust linkages between international ABS frameworks and intellectual property law.

The CBD and the Nagoya Protocol represent significant advancements in the recognition and protection of the rights of indigenous peoples to their traditional knowledge. They enshrine the principles of prior informed consent, mutually agreed terms, and fair benefit-sharing as essential components of any access to traditional knowledge and genetic resources. However, the true efficacy of these treaties depends on their effective implementation at the national level and the capacity of indigenous communities to assert their rights within these frameworks. Addressing gaps, particularly in relation to intellectual property rights and benefit-sharing, remains crucial for ensuring that the



legal protections afforded by the CBD and the Nagoya Protocol translate into tangible benefits for indigenous peoples.

### Comparative analysis of-India, Brazil, and Peru

India, Brazil, and Peru were chosen for this analysis due to their diverse legal frameworks, significant indigenous populations, and influential roles in international biodiversity and indigenous rights discussions. Each country represents a distinct approach to protecting traditional knowledge and promoting fair benefit-sharing, reflecting their unique demographic contexts: India, with approximately 104 million indigenous people (about 8.6% of the total population), showcases comprehensive national

legislation such as the Biological Diversity Act (2002) and the Forest Rights Act (2006) [61]. Brazil, home to around 1.6 million indigenous people (about 0.8% of the total population), leads with its Provisional Measure 2.186-16/2001 and National Policy on Traditional Knowledge [62]. Peru, with about 4.5 million indigenous people (approximately 15% of the total population), implements Law No. 27811 and Law No. 29164 to align with international standards [63]. Their varied implementation challenges and historical contexts offer valuable insights into the practical difficulties and successes in translating international principles into effective national policies (Table 2).

**Table 2:** Comparative analysis of-India, Brazil, and Peru

Country	Legislation and implementation	Key features	Challenges and limitations
India	Biological Diversity Act, 2002	Access and Benefit-Sharing (ABS): Requires Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) for access to biological resources	Implementation gaps: Limited awareness and capacity at the local level
	Forest Rights Act, 2006	Recognition of rights: Forest Rights Act recognizes the rights of indigenous communities over forest land and resources	Complex bureaucratic processes: Challenges in obtaining PIC and establishing MAT
		Traditional Knowledge: Provides for the protection of traditional knowledge related to biological resources	Enforcement issues: Difficulties in enforcing benefit-sharing agreements and protecting traditional knowledge from biopiracy
Brazil	Provisional measure 2.186-16/2001	Access and Benefit-sharing (ABS): Requires authorization from the National Institute for the Environment and Renewable Natural Resources (IBAMA) for access to genetic resources	Legal uncertainty: Provisional measures have faced challenges and revisions
	National policy on traditional knowledge	Benefit-sharing agreements: Mandates fair and equitable benefit-sharing with indigenous communities	Implementation variability: Inconsistent application and enforcement across regions
		Protection of indigenous knowledge: National Policy emphasizes the protection and promotion of traditional knowledge	Resource constraints: Limited resources for effective monitoring and enforcement
Peru	Law No. 27811 on the protection of the cultural heritage of indigenous peoples	Access and Benefit-sharing (ABS): Requires prior informed consent and benefit-sharing agreements with indigenous peoples for genetic resources	Implementation challenges: Difficulties in enforcing regulations in remote areas
	Law No. 29164 on Access to Genetic resources and benefit-sharing	Protection of traditional knowledge: Law No. 27811 provides for the protection of indigenous cultural heritage and traditional knowledge	Legal and administrative barriers: Complex legal requirements can be a barrier for indigenous communities
		Consultation mechanisms: Emphasizes the need for consultations with indigenous communities	Coordination issues: Need for better coordination between national and local authorities

### The role of the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), adopted by the General Assembly in September 2007, stands as a seminal international instrument in the recognition and protection of indigenous rights. UNDRIP represents a profound acknowledgment of the distinct rights and status of indigenous peoples, setting forth a comprehensive framework that addresses various aspects of their rights, including self-determination, land and resource management, and cultural preservation [64].

**Self-determination and autonomy:** One of the core principles enshrined in UNDRIP is the right to self-determination. This right, articulated in Article 3, affirms

that indigenous peoples have the right to freely determine their political status and pursue their economic, social, and cultural development [65]. This provision empowers indigenous communities to make autonomous decisions regarding their governance structures, cultural practices, and socioeconomic development, thereby reinforcing their agency and self-governance.

**Land and resource rights:** UNDRIP places significant emphasis on the recognition of indigenous land and resource rights. Article 26 asserts that indigenous peoples have the right to the lands, territories, and resources that they have traditionally owned, occupied, or otherwise used [66]. This article underscores the necessity of recognizing indigenous land claims and ensuring that their traditional

territories are not subjected to unauthorized exploitation. Furthermore, Article 32 mandates that states seek the Free, Prior, And Informed Consent (FPIC) of indigenous peoples before undertaking projects affecting their lands or resources [67]. This consent mechanism is pivotal in safeguarding indigenous rights against encroachments and ensuring that their participation in decision-making processes is both meaningful and respected.

**Cultural preservation:** The Declaration also addresses the preservation of indigenous cultures and traditional knowledge. Article 11 recognizes the right of indigenous peoples to practice and revitalize their cultural traditions and customs [68]. It further asserts the right to protect their cultural heritage, including traditional knowledge and expressions. This provision is crucial for the safeguarding of indigenous languages, cultural practices, and traditional knowledge systems, which are integral to their identities and ways of life.

**Health and education:** UNDRIP also highlights the rights of indigenous peoples to health and education. Article 24 affirms the right of indigenous peoples to their traditional medicines and practices, as well as access to culturally appropriate health services [67]. Additionally, Article 14 emphasizes the right of indigenous children to access education in their own culture and language, which is essential for the preservation and transmission of their cultural heritage [69].

**Implementation and challenges:** Despite the robust framework provided by UNDRIP, its implementation presents significant challenges. The Declaration itself is non-binding, meaning it does not impose legal obligations on states but rather serves as a guiding set of principles. The effectiveness of UNDRIP largely depends on the willingness of states to incorporate its provisions into national legislation and policy. Many indigenous communities continue to face obstacles in realizing their rights due to systemic inequalities, legal and administrative barriers, and ongoing disputes over land and resource claims.

The United Nations Declaration on the Rights of Indigenous Peoples represents a landmark achievement in international human rights law, offering a comprehensive and principled framework for the recognition and protection of indigenous rights. Its emphasis on self-determination, land and resource rights, cultural preservation, and access to health and education underscores the global commitment to addressing historical injustices and supporting the well-being and autonomy of indigenous peoples. However, translating these principles into concrete and effective measures remains a critical challenge, necessitating continued advocacy, legal reform, and collaborative efforts between states and indigenous communities.

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) provides a robust framework for recognizing and protecting the rights of indigenous communities over their traditional knowledge.

This recognition is embedded in several key provisions of the Declaration, reflecting the international commitment to respecting and safeguarding indigenous cultures, practices, and intellectual heritage.

**Protection of cultural heritage:** Article 11 of UNDRIP specifically addresses the protection and preservation of indigenous cultural heritage, including traditional knowledge. It asserts that indigenous peoples have the right to practice and revitalize their cultural traditions and customs. This encompasses traditional knowledge as an integral part of indigenous cultural heritage, affirming that such knowledge must be safeguarded and respected.

**Control over traditional knowledge:** Article 31 further emphasizes the rights of indigenous peoples to their cultural heritage, including their traditional knowledge and cultural expressions [66]. It establishes that indigenous communities have the right to maintain, control, protect, and develop their cultural heritage and traditional knowledge. This provision underscores the principle that indigenous peoples are the primary custodians of their traditional knowledge and that any use or dissemination of this knowledge should occur with their explicit consent.

**Free, Prior, and Informed Consent (FPIC):** The principle of Free, Prior, and Informed Consent, outlined in Article 32, plays a crucial role in the protection of traditional knowledge. It mandates that states must seek the consent of indigenous peoples before undertaking any activities or projects that may affect their lands, territories, and resources, which include traditional knowledge. This provision ensures that indigenous communities are not only informed but also have a say in decisions that impact their traditional knowledge and practices.

**Access to benefits:** While not explicitly detailed in UNDRIP, the concept of equitable benefit-sharing, which aligns with the Declaration's principles, is crucial for the protection of traditional knowledge. Indigenous peoples have the right to fair and equitable sharing of benefits arising from the use of their traditional knowledge. This principle is vital in addressing issues related to bio-piracy and ensuring that indigenous communities receive appropriate recognition and compensation for the commercial use of their traditional knowledge.

**Preservation and transmission:** UNDRIP recognizes the importance of preserving and transmitting traditional knowledge for future generations. Article 14 underscores the right of indigenous children to education in their own culture and language, which is essential for the intergenerational transmission of traditional knowledge. This provision supports the continuity and resilience of indigenous knowledge systems by ensuring that younger generations are educated within their cultural context.

**International frameworks and linkages:** UNDRIP aligns with other international frameworks that support the protection of traditional knowledge, such as the Convention on Biological Diversity (CBD) and its Nagoya Protocol. These agreements reinforce the principles of FPIC and

benefit-sharing, complementing the rights articulated in UNDRIP and providing additional mechanisms for safeguarding traditional knowledge in the context of biodiversity and genetic resources.

The United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) provides a comprehensive framework for recognizing and protecting the rights of indigenous communities over their traditional knowledge. By affirming indigenous peoples' control, protection, and development of their cultural heritage, ensuring their consent in related activities, and promoting equitable benefit-sharing, UNDRIP establishes essential principles for safeguarding traditional knowledge. However, the effective implementation of these rights requires continued commitment from states, robust legal frameworks, and active participation of indigenous communities to ensure that their traditional knowledge is respected and preserved.

### **Ethical and legal challenges in protecting indigenous knowledge**

Biopiracy: Biopiracy refers to the unauthorized or unfair appropriation of biological resources and traditional knowledge by individuals or corporations, often from indigenous communities, without adequate recognition or compensation [70]. This practice undermines the rights of indigenous communities and can lead to economic and cultural losses.

Examples of Biopiracy:

- **Hoodia patent:** The San people of Southern Africa used the Hoodia plant to suppress appetite. Despite its traditional use, the plant was patented by the South African Council for Scientific and Industrial Research and licensed to pharmaceutical companies [71]. Initially, the San people did not receive recognition or compensation. However, advocacy efforts led to a settlement directing some profits to the San communities [72].
- **Ayahuasca patent:** Various companies filed patents to commercialize ayahuasca, a traditional Amazonian plant-based brew used for spiritual and medicinal purposes [73]. These patents were often filed without consulting the indigenous groups that used ayahuasca for generations [74].
- **Neem tree patent:** The U.S. Department of Agriculture and W.R. Grace were granted a patent in the 1990s for neem tree extracts as a pesticide, overlooking its long-standing traditional use in India [75,76]. Indian activists challenged the patent, which was revoked in 2000 [77].
- **Turmeric patent:** In the 1990s, the University of Mississippi Medical Center was granted a patent for turmeric's wound-healing properties, ignoring its centuries-old traditional use in India [78,79]. After opposition from Indian activists, the patent was revoked in 1997 [80].

- **Basmati rice patent:** RiceTec patented a variety of basmati rice in the 2000s, ignoring the traditional cultivation in India [80]. A legal battle ensued, leading to the retraction of the patent [81].
- **Wheat patent:** An American company filed a patent in the 2000s for a wheat variety developed using traditional Indian wheat, overlooking indigenous contributions [82]. This patent faced criticism for not recognizing traditional knowledge [83].

These cases highlight the urgent need for legal frameworks, such as the Biological Diversity Act [2002], to protect traditional knowledge and ensure fair compensation. India's efforts to strengthen its legal mechanisms are crucial in safeguarding indigenous rights.

**Access and Benefit-sharing (ABS) mechanisms:** Access and Benefit-sharing (ABS) aims to ensure that the benefits arising from the utilization of biological resources and traditional knowledge are shared fairly with the communities that developed them [84]. ABS mechanisms address inequities from biopiracy by ensuring Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and equitable benefit-sharing [85].

### **Key elements of ABS**

- **Prior Informed Consent (PIC):** Users must obtain consent from indigenous communities before accessing genetic resources. This ensures transparency and allows communities to agree on the terms of use [86].
- **Mutually Agreed Terms (MAT):** Once consent is obtained, MAT outlines the conditions for resource use and benefit-sharing, which may include both monetary and non-monetary benefits [87].
- **Equitable benefit-sharing:** ABS ensures that benefits, including royalties, licensing fees, technology transfer, and collaborative research, are shared fairly with indigenous communities [54].

### **Legal frameworks supporting ABS**

- **Convention on Biological Diversity (CBD):** Establishes the foundation for ABS, emphasizing fair benefit-sharing and countries' rights to regulate access to their genetic resources [87].
- **Nagoya protocol:** Provides detailed guidelines for implementing ABS, reinforcing the need for PIC and MAT to enhance transparency [88].
- **National legislation:** Many countries have national laws to operationalize ABS principles. For example, India's Biological Diversity Act (2002) regulates access to biological resources and ensures benefit-sharing.
- **Effective ABS mechanisms also include monitoring and enforcement provisions to ensure compliance with agreed terms, thereby protecting indigenous rights.**

## Consent and participation

The importance of obtaining Prior Informed Consent (PIC): Obtaining PIC from indigenous communities is crucial for several reasons:

- Respect for indigenous rights: PIC honors the sovereignty of indigenous peoples, acknowledging their authority over their knowledge and resources [89].
- Ethical considerations: It prevents the exploitation of traditional knowledge, promoting ethical practices and fostering trust [90].
- Legal compliance: International treaties like the CBD and Nagoya Protocol mandate the need for PIC, establishing legal frameworks for accessing genetic resources.
- Cultural sensitivity: PIC ensures that traditional knowledge is used in ways aligned with the community's cultural values, preventing misuse [91].
- Empowerment: By giving communities a voice in decision-making, PIC empowers them to negotiate terms and participate in benefit-sharing [92].
- Prevention of biopiracy: PIC protects indigenous knowledge from unauthorized use and exploitation [93].
- Building trust: It fosters transparency, leading to more effective and mutually beneficial partnerships [94].
- PIC is fundamental for respecting indigenous rights, ensuring ethical practices, and avoiding biopiracy. It empowers communities and facilitates fair benefit-sharing.
- Challenges in achieving meaningful participation of indigenous peoples in decision-making processes
- Achieving meaningful participation of indigenous peoples involves overcoming several challenges:
- Historical marginalization: Indigenous peoples have historically been excluded from decision-making, creating barriers to engagement [95].
- Power imbalances: Significant power disparities exist between indigenous communities and external entities, affecting the fairness of negotiations [96].
- Cultural and language barriers: Decision-making processes may not always accommodate the cultural practices and languages of indigenous communities [97].
- Lack of capacity and resources: Indigenous communities often lack access to legal expertise, technical knowledge, and financial support.
- Legal and institutional barriers: Existing laws may not support indigenous participation or be inadequately enforced, complicating engagement.
- Tokenism: Superficial inclusion of indigenous peoples

in decision-making without genuine influence can undermine participation.

- Lack of recognition: Indigenous rights to self-determination, land, and resources may not be fully recognized, limiting effective participation [98].
- Conflicts of interest: External stakeholders may prioritize their agendas, leading to decisions that do not reflect indigenous values.
- Historical trauma and distrust: Past exploitation and broken promises have led to a lack of trust between indigenous communities and external actors [99].
- Inadequate consultation: Proper participation requires more than consultation; it involves engagement that allows communities to influence outcomes.

Overcoming these challenges is vital for inclusive decision-making processes that respect and incorporate indigenous rights. Addressing historical marginalization, building trust, ensuring cultural sensitivity, and fostering genuine participation are key to empowering indigenous communities.

## Case studies

A case study is a detailed, in-depth analysis of a particular instance, event, or entity, used to explore and understand broader principles, theories, or issues [100]. In the context of doctrinal legal research, case studies involve examining specific legal cases, disputes, or regulatory issues to elucidate the application and impact of legal doctrines, principles, or frameworks. These studies aim to uncover insights about the effectiveness, challenges, and implications of legal norms and practices within real-world contexts. By focusing on concrete examples, case studies allow researchers to evaluate how laws are interpreted and enforced, and they provide practical lessons that inform policy-making, legal theory, and future legal developments.

### Neem tree patent case

**Background:** The neem tree (*Azadirachta indica*) is native to the Indian subcontinent and has been used for centuries in traditional Indian medicine, agriculture, and daily life. Known for its anti-bacterial, anti-fungal, and pesticidal properties, neem has been an essential part of Ayurvedic practices. Indigenous communities have long relied on neem oil, bark, leaves, and extracts for treatments against ailments and for use as a natural pesticide [101].

**The patent controversy:** In the 1980s and 1990s, interest in neem's properties grew in the West, leading to several patents being filed by international corporations on products derived from neem. One of the most controversial was a European patent granted to the U.S. Department of Agriculture and the multinational corporation W.R. Grace in 1994. The patent covered a method for extracting neem oil and using it as a fungicide, effectively granting them exclusive commercial rights over a process that had been used in India for centuries.

This patent provoked outrage in India and among

environmental activists worldwide, who saw it as a clear instance of biopiracy—the misappropriation of traditional knowledge without proper acknowledgment or benefit-sharing with the indigenous communities.

**Challenges and response:** The neem patent case mobilized a coalition of Indian farmers, scientists, and international activists to challenge the patent. A key player in this movement was the India-based Research Foundation for Science, Technology, and Ecology (RFSTE), along with other organizations like the International Federation of Organic Agriculture Movements (IFOAM). They argued that the process described in the patent lacked novelty since it was already part of traditional knowledge in India.

In 1995, a legal opposition was filed with the European Patent Office (EPO) against W.R. Grace's patent on the grounds that the use of neem oil for fungicidal purposes was well-documented in ancient Indian texts and oral traditions. After a lengthy legal battle, the EPO finally revoked the patent in 2000, citing "lack of inventive step" and confirming that the fungicidal use of neem was not a novel discovery but rather an established traditional practice.

**Lessons learned:**

1. **Power of traditional knowledge documentation:** The neem case underscored the importance of documenting traditional knowledge to defend it against wrongful patent claims. This led to efforts in India, such as the creation of the Traditional Knowledge Digital Library (TKDL), to catalog ancient practices systematically.
2. **Limitations of patent systems:** The case revealed how patent systems can overlook traditional knowledge, especially when it comes from cultures that transmit information orally or through practice rather than formal scientific documentation. It called for reforms in global intellectual property laws to recognize and protect indigenous knowledge.
3. **International collaboration:** The successful revocation of the neem patent illustrated the impact of international activism and collaboration. By bringing together Indian farmers, scientists, and global organizations, the case highlighted how collective action can defend indigenous rights and challenge biopiracy.

**Impact and significance:** The neem patent case became a landmark victory for indigenous rights and the fight against biopiracy. It set a precedent for challenging patents that seek to exploit traditional knowledge without recognition or benefit-sharing. This case also brought global attention to the need for ethical practices in accessing and using traditional knowledge, leading to more stringent evaluation of patent applications involving natural products.

**Current relevance:** The neem case continues to influence debates on intellectual property rights, traditional knowledge, and biopiracy. It reinforced the importance of the Convention on Biological Diversity (CBD) and the Nagoya Protocol, which advocate for fair and equitable

benefit-sharing with indigenous communities. The case remains a vital reference point in discussions on how to protect the rights of indigenous peoples and ensure that traditional knowledge is not misappropriated for commercial gain.

### **Turmeric patent case**

**Background:** Turmeric (*Curcuma longa*) is a plant native to the Indian subcontinent, widely recognized for its medicinal, culinary, and cultural significance. For centuries, it has been used in India in traditional practices like Ayurveda, particularly for its wound-healing, anti-inflammatory, and antiseptic properties. This indigenous knowledge has been passed down through generations and is deeply embedded in Indian culture [102].

**The patent controversy:** In 1995, 2 researchers at the University of Mississippi Medical Center were granted a U.S. patent (Patent No. 5,401,504) for the "use of turmeric powder as a wound-healing agent." The patent covered the use of turmeric for healing external wounds, a practice that had been well-documented and used for centuries in India. The patent effectively granted exclusive rights over the use of turmeric in wound healing, which sparked immediate concern and outrage in India. The Indian Council of Scientific and Industrial Research (CSIR) viewed the patent as an act of biopiracy, as it sought to claim ownership over traditional knowledge that had existed long before the patent was filed.

**Challenges and response:** CSIR filed a formal challenge against the patent with the United States Patent and Trademark Office (USPTO), arguing that the use of turmeric for wound healing was "prior art" and not a novel invention. To support their claim, they provided documented evidence, including ancient Sanskrit texts and other literature, demonstrating that the therapeutic use of turmeric had been part of traditional Indian medicine for thousands of years.

In 1997, after reviewing the evidence presented by CSIR, the USPTO revoked the patent. The decision marked a significant victory for India and for the protection of traditional knowledge from misappropriation. It underscored those ancient practices and traditional knowledge, when documented, could serve as a basis to challenge patents that seek to exploit such knowledge without proper recognition.

**Lessons learned:**

1. **Documentation of traditional knowledge:** The turmeric case highlighted the importance of systematically documenting traditional knowledge to provide evidence against biopiracy and wrongful patent claims. This led to efforts in India to compile traditional knowledge into accessible databases, such as the Traditional Knowledge Digital Library (TKDL).
2. **Limitations of patent systems:** The case revealed the inadequacies in international patent systems, which often fail to recognize or protect traditional knowledge,

especially when it originates from oral traditions. It emphasized the need for reforms in intellectual property laws to prevent the misappropriation of indigenous knowledge.

3. International advocacy for traditional knowledge: The successful challenge against the turmeric patent showed the potential of international legal mechanisms to advocate for the rights of indigenous communities and protect traditional knowledge from commercial exploitation.

**Impact and significance:** The turmeric patent case became a landmark example in the global fight against biopiracy. It demonstrated that traditional knowledge, even if ancient and widely known in certain regions, can be vulnerable to appropriation through the patent system. The revocation of the turmeric patent helped strengthen India's position in advocating for changes in international intellectual property laws to better protect traditional knowledge.

**Current relevance:** The turmeric case continues to serve as a precedent in discussions on intellectual property rights and the protection of traditional knowledge. It paved the way for India and other countries to create mechanisms like the TKDL, aimed at documenting traditional knowledge and making it accessible to patent offices worldwide to prevent future instances of biopiracy. The case remains a powerful reminder of the need for fair recognition, respect, and benefit-sharing for indigenous practices and knowledge systems.

### Hoodia case

**Background:** *Hoodia gordonii* is a succulent plant native to the Kalahari Desert in Southern Africa [103,104]. For centuries, the indigenous San people (also known as Bushmen) have used Hoodia to stave off hunger and thirst during long hunting trips. This traditional knowledge was passed down orally through generations and became an integral part of their culture and survival in the harsh desert environment.

In the 1990s, the Council for Scientific and Industrial Research (CSIR) in South Africa, while researching indigenous plants for potential commercial use, discovered the appetite-suppressant properties of Hoodia. CSIR identified a specific compound, named P57, that could potentially be developed into a commercial weight-loss product. They subsequently patented this compound in 1996 without consulting or informing the San people.

**The patent controversy:** CSIR later licensed the patent for P57 to the UK-based pharmaceutical company Phytopharm, which then sold the commercialization rights to Pfizer, the global pharmaceutical giant. This sequence of events raised concerns about biopiracy and the misappropriation of indigenous knowledge. The San people, who had used Hoodia for its appetite-suppressing properties for centuries, were neither informed nor compensated for the use of their traditional knowledge.

The controversy sparked a global outcry and became a

symbol of the ethical issues surrounding the exploitation of indigenous knowledge by commercial entities. Activists and indigenous rights groups criticized CSIR for violating the San people's rights and ignoring the principles of Free, Prior, and Informed Consent (FPIC).

**Challenges and response:** In response to mounting pressure and public scrutiny, CSIR entered into negotiations with the San people. In 2003, a historic agreement was reached between CSIR and the San, which recognized the San as the rightful holders of traditional knowledge regarding Hoodia. The agreement stipulated that the San would receive a percentage of the royalties from the commercialization of Hoodia-based products.

Despite the agreement, challenges remained in ensuring the San community received meaningful benefits. Issues such as fair distribution of funds, transparency, and long-term support for the San people's development persisted. Additionally, the global demand for Hoodia led to overharvesting, raising concerns about the sustainability of the plant and the long-term interests of the indigenous communities.

**Lessons learned:**

1. Importance of Free, Prior, and Informed Consent (FPIC): The Hoodia case highlighted the necessity of obtaining FPIC from indigenous communities before utilizing their traditional knowledge for commercial purposes. This principle ensures that indigenous peoples have a say in how their knowledge is used and can negotiate fair benefit-sharing.
2. Benefit-sharing agreements: The case demonstrated that benefit-sharing agreements are essential for recognizing indigenous rights. Although CSIR eventually established such an agreement, it underscored the complexities and challenges involved in ensuring that these benefits reach the communities fairly.
3. Sustainability and conservation: The increased demand for Hoodia raised concerns about the environmental sustainability of harvesting the plant. The case emphasized the need for regulations to prevent overexploitation and ensure that commercial use aligns with environmental conservation.

**Impact and significance:** The Hoodia case was a landmark in the fight against biopiracy, setting a precedent for the protection of indigenous knowledge and equitable benefit-sharing. The agreement between CSIR and the San people was one of the first instances of a formal benefit-sharing arrangement that recognized the rights of an indigenous community over their traditional knowledge. It highlighted the importance of implementing legal frameworks that respect indigenous rights and promote ethical practices in research and commercialization.

**Current relevance:** Today, the Hoodia case continues to influence international discourse on biopiracy, intellectual property rights, and indigenous knowledge. It underscores

the importance of frameworks such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, which advocate for the equitable sharing of benefits arising from the use of genetic resources and traditional knowledge. The case remains a cautionary tale, illustrating the ongoing challenges in protecting indigenous rights and ensuring that traditional knowledge is used in a way that is fair, transparent, and sustainable.

### Basmati rice patent case

**Background:** Basmati rice is a variety of long-grain aromatic rice that has been cultivated for centuries in the Indian subcontinent, particularly in the regions of India and Pakistan. Known for its unique flavor, aroma, and grain texture, Basmati rice holds cultural, agricultural, and economic significance in these regions. It is considered a premium variety, commanding a high price in the global market and representing an essential part of the agricultural heritage of India and Pakistan [103].

**The patent controversy:** In 1997, a Texas-based company, RiceTec Inc., was granted a patent by the United States Patent and Trademark Office (USPTO) (U.S. Patent No. 5,663,484) for certain “novel” strains of Basmati rice and associated methods of breeding them. RiceTec claimed that their strain was a cross between traditional Basmati varieties and other types of rice. This patent effectively granted RiceTec exclusive rights over marketing certain strains of Basmati rice in North America, using the name “Basmati”.

The patent stirred controversy and outrage in India and Pakistan. Governments, farmers, and activists viewed this as an act of biopiracy, arguing that RiceTec was misappropriating traditional knowledge and the centuries-old heritage of Basmati rice cultivation. They feared that the patent could undermine the livelihoods of farmers in the Indian subcontinent and dilute the unique identity of Basmati rice.

**Challenges and response:** The Indian government, along with farmer organizations and advocacy groups, launched a formal challenge against the patent, arguing that it was based on traditional varieties of Basmati rice developed by farmers over generations. They contended that the patent did not meet the criteria of novelty or inventiveness and that it infringed upon the Geographical Indications (GIs) associated with Basmati rice from India and Pakistan.

After years of legal and diplomatic efforts, RiceTec withdrew several claims from its patent. The USPTO subsequently invalidated many of the contested claims, including those that tried to label the strains as “Basmati.” However, RiceTec retained some claims related to specific rice lines and breeding methods. India also intensified its efforts to secure a GI tag for Basmati rice in international markets to protect the name and the traditional knowledge associated with its cultivation.

**Lessons learned:**

1. Geographical Indications (GI) as a protective tool: The

Basmati rice case demonstrated the importance of GI tags in safeguarding traditional agricultural products linked to specific regions. The case prompted India and Pakistan to seek GI protection for Basmati rice in international markets to prevent unauthorized use of the name.

2. Limitations of patent systems: The controversy highlighted the inadequacies of traditional patent systems in recognizing and protecting products developed through collective traditional knowledge. It emphasized the need for legal mechanisms that respect the cultural and geographical heritage of agricultural products.

3. International collaboration: The case underscored the necessity for cooperation between countries, particularly India and Pakistan, in protecting shared traditional knowledge from biopiracy.

**Impact and significance:** The Basmati rice patent case became a landmark example of biopiracy, illustrating how traditional knowledge and agricultural heritage could be appropriated through intellectual property laws. The challenge to RiceTec’s patent led to a greater emphasis on protecting traditional knowledge and fostering international discussions on the ethical use of such knowledge. It also brought attention to the importance of GIs as a means of protecting culturally significant products in the global marketplace.

**Current relevance:** Today, the Basmati rice case continues to influence policies on intellectual property rights, traditional knowledge, and geographical indications. India has since obtained GI status for Basmati rice in various countries, strengthening its position in protecting the rice’s unique identity. The case remains a critical reference point in global debates on biopiracy and the protection of indigenous agricultural products, underscoring the need for legal frameworks that recognize and preserve the heritage of traditional farming communities.

### Quinoa case

**Background:** Quinoa (*Chenopodium quinoa*) is a grain that has been cultivated for thousands of years by indigenous peoples in the Andean regions of Bolivia, Peru, and Ecuador. This “superfood” is known for its high nutritional value, including a complete protein profile, making it a valuable food source. Traditionally, quinoa has been integral to the culture, diet, and agriculture of the Andean communities. In the early 2000s, the global demand for quinoa surged, drawing international attention to its unique properties and nutritional benefits [105].

**The patent controversy:** In the 1990s, two researchers from Colorado State University (CSU) in the United States obtained a patent for a specific quinoa variety (U.S. Patent No. 5,304,718). They had identified and developed this variety for cultivation in North America. The patent granted exclusive rights over the production and sale of this particular strain, raising concerns about bio-piracy and the misappropriation of indigenous knowledge.

The controversy stemmed from the perception that the patent indirectly claimed ownership over a crop that was originally cultivated and developed by Andean farmers over millennia.

**Challenges and response:** Indigenous communities and activists argued that the patent violated their rights and that it was an example of bio-piracy. They contended that the patent did not recognize the traditional knowledge and efforts of the Andean farmers in developing quinoa's genetic diversity. This case led to heightened awareness and global discourse on the ethics of patenting traditional crops and the need for mechanisms to protect the rights of indigenous farmers.

As the quinoa market expanded, the demand for benefit-sharing arrangements with the indigenous communities responsible for quinoa's diversity also increased. However, challenges remained in balancing the interests of local farmers with the global commercial market and in ensuring that benefit-sharing agreements were effectively implemented.

**Lessons learned:**

**Need for protecting farmers' rights:** The Quinoa case illustrated the necessity of establishing legal protections for farmers and indigenous communities to maintain control over their traditional crops and agricultural practices.

**Informed consent and benefit-sharing:** It highlighted the importance of obtaining Free, Prior, and Informed Consent (FPIC) from indigenous communities before commercializing traditional knowledge and biological resources.

**Importance of International frameworks:** The controversy underscored the role of international treaties like the Convention on Biological Diversity (CBD) and the Nagoya Protocol in advocating for fair benefit-sharing and safeguarding traditional knowledge.

**Impact and significance:** The Quinoa case became emblematic of the larger issues of biopiracy, commercialization of traditional knowledge, and food sovereignty. While the specific patent was not overturned, the public outcry prompted discussions on the ethical implications of patenting crops developed by indigenous peoples. It also highlighted the need for stronger international and national frameworks to protect traditional agricultural knowledge and ensure equitable benefit-sharing.

**Current relevance:** Today, the quinoa case continues to serve as a reference point in global discussions on biopiracy and indigenous rights. It supports ongoing efforts to develop legal mechanisms that recognize the contributions of indigenous peoples to biodiversity and promote fair benefit-sharing practices. Furthermore, it emphasizes the need for policies that protect traditional crops and support sustainable agricultural practices in indigenous communities.

## Wheat patent case

**Background:** The Wheat Patent case centers on a traditional Indian wheat variety known as "Nap Hal." This wheat has been cultivated in India for centuries and is prized for its unique properties, including its low-gluten content, which makes it ideal for certain traditional Indian foods. In 1997, the European Patent Office (EPO) granted a patent to the multinational company Monsanto for a wheat variety they developed, which had genetic characteristics similar to the Nap Hal variety [106].

**The patent controversy:** Monsanto's patent covered the use of this wheat variety for making bread and bakery products. Indian farmers, activists, and the government viewed this as an act of biopiracy, arguing that the patented variety was not a new invention but rather a form of traditional Indian wheat that had been cultivated for generations. The patent effectively appropriated traditional knowledge and agricultural heritage, granting exclusive rights over a variety that had been a part of India's agricultural landscape for centuries.

**Challenges and response:** In response to the patent grant, India, supported by environmental groups and activists, mounted a legal and political campaign to challenge the patent. They argued that the patent was based on existing knowledge of an indigenous variety and did not meet the criteria of novelty or inventiveness required for patents. After years of advocacy and legal effort, the EPO revoked the patent in 2004, agreeing that the wheat variety had been developed using knowledge that was already in the public domain.

**Lessons learned:**

1. **Inadequacies of intellectual property laws:** The wheat patent case revealed that current intellectual property laws, particularly patents, often fail to recognize and protect traditional agricultural knowledge. They can inadvertently grant exclusive rights over resources that indigenous communities have developed over centuries.
2. **Need for documentation of traditional knowledge:** One of the significant challenges faced in the case was proving the prior existence and traditional use of the wheat variety. The case demonstrated the need for comprehensive documentation of traditional knowledge to prevent biopiracy.
3. **Importance of National and International legal safeguards:** The case underlined the necessity for countries to implement strong laws and frameworks, such as the Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act) in India, to safeguard traditional agricultural resources and farmers' rights.

**Impact and significance:** The revocation of Monsanto's patent on the Nap Hal wheat variety was a significant victory for India and global activists advocating for the



protection of traditional knowledge and biodiversity. It emphasized the need for intellectual property systems that accommodate traditional agricultural practices and recognize the collective knowledge of farming communities. Additionally, the case reinforced the importance of benefit-sharing mechanisms and respecting the rights of farmers and indigenous communities over their traditional crops.

**Current relevance:** The Wheat Patent case continues to serve as an example in the ongoing global debate over biopiracy, intellectual property rights, and the need to protect traditional knowledge and biodiversity. It supports the argument for stronger legal frameworks that prevent the misappropriation of indigenous and farmer-developed resources. The case also underscores the significance of international agreements, such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol, in promoting equitable benefit-sharing and protecting traditional knowledge.

### Ayahuasca patent case

**Background:** Ayahuasca is a traditional psychoactive brew used for centuries by indigenous tribes in the Amazon Basin, including communities in Peru, Brazil, Colombia, and Ecuador. Made from the *Banisteriopsis caapi* vine and other plant ingredients, ayahuasca plays a vital role in indigenous spirituality, healing practices, and cultural identity. Its significance extends beyond medicinal uses, encompassing religious and community practices [107].

**The patent controversy:** In 1986, an American citizen, Loren Miller, was granted a U.S. patent (U.S. Plant Patent No. 5,751) for a specific variety of the *Banisteriopsis caapi* vine, labeling it as a new and distinct “invented” variety. The patent essentially gave Miller exclusive rights over the vine’s use and cultivation. The patenting of a plant that was not new, and which had been cultivated and used by indigenous Amazonian communities for generations, raised alarms among indigenous groups and activists. They saw this as an act of biopiracy—an exploitation of traditional knowledge without proper acknowledgment or benefit-sharing.

**Challenges and response:** The Amazonian indigenous groups, with support from various non-governmental

organizations, argued that the patent violated their rights and the collective ownership of their traditional knowledge. After years of advocacy and legal challenges, the U.S. Patent and Trademark Office (USPTO) re-examined the case. In 1999, the USPTO revoked the patent, concluding that the plant was not a new invention, but rather a variety that had existed and been known to the indigenous people for centuries.

**Lessons learned:**

**Limitations of Existing Intellectual Property Rights (IPR):** The Ayahuasca case highlighted how conventional IPR systems, such as patents, often fail to adequately protect traditional knowledge, especially knowledge collectively held by indigenous communities.

**Need for informed consent:** The case underscored the necessity for obtaining the Free, Prior, and Informed Consent (FPIC) of indigenous communities before any commercialization of their traditional knowledge.

**Collective mobilization and advocacy:** The successful challenge to the patent demonstrated the power of collective action by indigenous communities and international advocacy groups in defending traditional knowledge.

**Impact and significance:** The Ayahuasca patent case is a landmark in the fight against biopiracy, emphasizing the need for stronger protections for traditional knowledge at both national and international levels. It also spurred discussions about incorporating customary laws and practices into intellectual property regimes to safeguard indigenous knowledge. The revocation of the patent reinforced the idea that traditional knowledge is a collective heritage of indigenous peoples and should not be monopolized for private gain without proper acknowledgment and equitable benefit-sharing.

**Current relevance:** This case continues to serve as a reference point in international debates on biodiversity, traditional knowledge, and the rights of indigenous peoples, highlighting the importance of frameworks like the Convention on Biological Diversity (CBD) and the Nagoya Protocol in ensuring the rights and knowledge of indigenous communities are respected (Table 3).

**Table 3:** Lesson learned and best practices

Lesson learned	Best practice
Recognize and respect traditional knowledge	Engage with indigenous communities to understand and respect their knowledge systems. Establish formal agreements to acknowledge their contributions
Ensure Free, Prior, and Informed Consent (FPIC)	Implement comprehensive consultation processes. Provide clear information, obtain genuine consent, and document it. Ensure communities have the right to withdraw consent
Implement fair benefit-sharing arrangements	Develop and enforce agreements outlining how benefits will be shared, including financial compensation and other support. Regularly review and adjust arrangements
Strengthen legal frameworks and protections	Advocate for and support the development of robust legal frameworks addressing traditional knowledge protection and compliance with international standards, such as the CBD and Nagoya Protocol
Promote transparency and accountability	Maintain open communication with indigenous communities. Provide regular updates and implement grievance mechanisms to address issues
Foster collaborative research and development	Engage indigenous experts in research design, implementation, and decision-making. Build respectful and inclusive partnerships.

Address historical injustices	Acknowledge and address historical exploitation and marginalization. Work towards reparative measures to support and empower indigenous communities
Enhance capacity building and support	Provide training, resources, and support to enhance indigenous communities' ability to participate and benefit from drug discovery projects
Integrate indigenous knowledge into modern science	Combine traditional knowledge with scientific methods. Promote interdisciplinary approaches and respectful collaboration between traditional practitioners and scientists
Advocate for global standards and best practices	Support international agreements and guidelines that promote ethical use of traditional knowledge and ensure fair benefit-sharing

## Discussion

### Policy recommendations for protecting traditional knowledge

**Reforming intellectual property laws:** Incorporate traditional knowledge protections: Amend patent laws to include Traditional Knowledge (TK) as a category for special consideration, preventing the patenting of already documented TK.

**Develop new IP categories:** Introduce sui generis systems tailored for TK protection, recognizing its unique attributes outside conventional IP rights.

**Enhance disclosure requirements:** Mandate patent applicants to disclose sources of biological resources and TK, including evidence of Free, Prior, and Informed Consent (FPIC) from indigenous communities.

**Strengthen enforcement:** Establish dedicated bodies to oversee TK compliance and provide legal remedies for unauthorized use.

### Strengthening legal mechanisms

**Implement Nagoya protocol:** Advocate for clearer guidelines and stricter enforcement to ensure countries follow Access and Benefit-sharing (ABS) principles.

**Support capacity building:** Provide technical and financial support to developing countries and indigenous communities to implement and benefit from the Nagoya Protocol.

**Promote International cooperation:** Encourage countries to harmonize national legislation with international agreements and share best practices.

**Enhance transparency:** Monitor and report on the implementation of international agreements to ensure accountability.

### Enhancing community rights and participation

**Enforce FPIC:** Legally require FPIC before using traditional knowledge, ensuring culturally appropriate consent.

**Empower communities:** Support education and resources to enable active participation in decision-making.

**Inclusive platforms:** Create forums for indigenous engagement with policymakers, researchers, and businesses.

**Provide legal support:** Assist communities in navigating IP and ABS issues, and provide resources for challenging unauthorized use.

### Promoting fair benefit-sharing

**Design transparent agreements:** Develop ABS agreements with clear benefit-sharing terms, ensuring full participation of indigenous communities.

**Monitor compliance:** Track TK use and ensure benefits are fairly distributed as agreed.

**Foster long-term partnerships:** Build ongoing relationships between businesses, researchers, and communities that support capacity-building and respect cultural heritage.

**Equitable distribution:** Ensure benefits are fairly distributed within communities, reflecting individual contributions and impacts.

These recommendations aim to protect traditional knowledge, ensure fair compensation, and support indigenous rights and participation.

## Conclusion

In conclusion, the integration of traditional knowledge into modern drug development necessitates the establishment of robust legal and ethical frameworks that respect and protect the rights of indigenous communities. Current intellectual property systems and Access and Benefit-sharing (ABS) mechanisms, despite efforts like the Convention on Biological Diversity (CBD) and the Nagoya Protocol, require significant reform to prevent exploitation and bio-piracy. Free, Prior, and Informed Consent (FPIC) must be central to these frameworks, ensuring that indigenous contributions are recognized and fairly compensated. Beyond legal protections, ethical considerations rooted in respect, transparency, and equity are vital in promoting a sustainable and inclusive approach to the use of traditional knowledge. By embedding these principles into both national and international policies, we can uphold indigenous rights, safeguard cultural and environmental integrity, and enhance the credibility of pharmaceutical innovations. Balancing innovation with justice is key to honouring the invaluable heritage of traditional knowledge while advancing scientific progress.

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### Conflict of Interest

The Authors declare that there is no conflict of interest.

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