
PRESERVING INDIGENOUS MEDICINAL KNOWLEDGE IN INDIA: AN ANALYSIS OF HEALTH RIGHTS AND INTELLECTUAL PROPERTY CHALLENGES

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ABSTRACT

This study examines the challenges in protecting Indigenous medicinal knowledge in India and its impact on health rights within the context of intellectual property regimes. It critically analyses the effectiveness of current legal frameworks, including the Patent Act, 1970 and the Biological Diversity Act, 2002, in safeguarding traditional medicinal practices against biopiracy and misappropriation. The research employs a doctrinal research approach to investigate the inadequacies of existing Intellectual Property Rights (IPR) systems in addressing the communal nature of Indigenous communities' access to traditional healthcare resources and their ability to maintain cultural practices. The study also evaluates international agreements like TRIPS and their implications for traditional knowledge protection. By synthesising insights from legal analysis and case studies, this research proposes alternative legal mechanisms and policy reforms. These recommendations aim to enhance the preservation of indigenous medicinal knowledge while ensuring equitable benefit-sharing and protecting health rights. The findings contribute to the ongoing discourse on balancing IPR protection with the rights of Indigenous communities, offering a comprehensive legal perspective on this critical issue in the Indian context.

I. INTRODUCTION

India, with its immense cultural and biological diversity, is a treasure trove of indigenous medicinal knowledge.¹ For centuries, traditional medicinal systems such as Ayurveda, Unani, Siddha and various folk practices have been integral to the health and well-being of communities across the country.² These traditional knowledge systems are often deeply embedded in the daily lives of indigenous populations, where they serve as primary healthcare resources, particularly in rural and remote regions.³ Beyond their healthcare value, this knowledge forms a significant part of the cultural identity and heritage of indigenous communities, representing centuries of wisdom and experience passed down orally from one generation to another.⁴

Despite its importance, indigenous medicinal knowledge is increasingly under threat due to various factors, including the modernisation of healthcare, commercial exploitation, and the encroachment of intellectual property regimes that do not recognise the unique nature of traditional knowledge, which is often exploited without the consent or benefit of the indigenous communities who are the original knowledge holders. One of the most alarming trends is biopiracy, where multinational corporations and researchers' appropriate traditional knowledge and genetic resources for commercial gain, often patenting them without any acknowledgement or compensation to the communities from whom the knowledge originated.⁵

The introduction of the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) has further complicated the preservation

¹ Kamlappa Ramakrishnappa, *Impact of Cultivation and Gathering of Medicinal Plants on Biodiversity: Case Studies from India* (Biotechnology Centre, Bangalore, India, Regional Office for Europe, Sustainable Development Department Group) <https://www.fao.org/4/y4586e/y4586e09.htm> accessed 09 October 2025.

² M.M. Pandey, Dubha Rastogi and A.K.S. Rawat, 'Indian Traditional Ayurvedic Systematic of Medicine and nutritional Supplementation' (2013) 2013 Evid Based Complement Alternat Med <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3705899/> accessed 09 October 2025.

³ Kavita S Philip, 'Indigenous Knowledge: Science and Technology Studies' in James D Wright (ed), *International Encyclopedia of the social & Behavioral Science* (2nd edn, Elsevier 2015) <https://www.sciencedirect.com/topics/social-sciences/indigenous-knowledge> accessed 08 October 2025.

⁴ Fulvio Mazzocchi, 'Western Science and Traditional Knowledge: Despite Their Variations, Different Forms of Knowledge Can Learn from Each Other' (2006) 7(5) EMBO Rep 463 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1479546/> accessed 06 October 2025.

⁵ Shahnaz Kaushar, 'BIO-PIRACY IN INDIA: A Practice of Patenting Traditional Knowledge for profit' (National Law University Nagpur (2023)) <https://www.nlunagpur.ac.in/PDF/Publications/5-Current-Issue/5.BIO-PIRACY%20IN%20INDIA%20A%20PRACTICE%20OF%20PATENTING%20TRADITIONAL%20KNOWLEDGE%20FOR%20PROFIT.pdf> accessed 07 October 2025.

of indigenous medicinal knowledge.⁶ TRIPS mandates the universal extension of patent terms and enforces strict IPR protection that are tailored to formal, documented innovations, primarily benefiting developed countries and multinational corporations. However, traditional knowledge, which is typically orally transmitted and community-owned, does not easily conform to these western-centric legal frameworks.⁷ This put the indigenous knowledge holders at a severe disadvantage, as they are unable to protect their heritage from being patented and commercialised by outsiders.⁸

India, being a signatory to TRIPS, has faced immense challenges in protecting its indigenous medicinal knowledge under the current global IPR regime. Although India has taken several steps, such as enacting the Biological Diversity Act, 2002, and setting up the Traditional Knowledge Digital Library (TKDL), these efforts have not been entirely successful in safeguarding traditional use of this knowledge.⁹

Additionally, the preservation of indigenous medicinal knowledge is also a critical health rights issue, for many Indigenous communities. This knowledge is the only affordable and accessible healthcare option available.¹⁰ The commercialisation and privatization of traditional medicinal resources under IPR framework can severely limit community access to these essential health resources.¹¹ As traditional medicines and practices are patented and sold at a premium, Indigenous population may be deprived of their own knowledge and resources, which were once freely available.¹² This not only violates their cultural rights but also threatens their health

⁶ Ministry of Commerce and Industry, *The Relationship the TRIPS Agreement and the Covention on Biological Diversity and the Protection of Traditional Knowledge* (Government of India, 2024) <https://www.commerce.gov.in/international-trade/india-and-world-trade-organization-wto/indian-submissions-in-wto/trade-related-aspects-of-intellectual-property-rightstrips/the-relationship-between-the-trips-agreement-and-the-convention-on-biological-diversity-and-the-protection-of-traditional-knowledge-2/#:~:text=Currently%2C%20the%20TRIPS%20Agreement%20contains,of%20the%20country%20of%20origin> accessed 11 October 2025.

⁷ Ajeet Mathur, 'Who Owns Traditional Knowledge?' 2002 (Indian Council for Research on International Economic Relations, New Delhi, and University of Tampere, Finland)

⁸ Akriti Gupta & Christ University, 'Protecting Indigenous Cultural Heritage: A Comparative Study of the Traditional Knowledge Bill of 2016 and 2022' (IJIRL, August 2023) <https://ijirl.com/wp-content/uploads/2023/08/PROTECTING-INDIGENOUS-CULTURAL-HERITAGE-A-COMPARATIVE-STUDY-OF-THE-TRADITIONAL-KNOWLEDGE-BILL-OF-2016-AND-2022.pdf> accessed 07 October 2025.

⁹ Ibid 5.

¹⁰ Dr. Sushma Sing 'Indian Traditional Medicinal Knowledge: A Critical Analysis (2022)' 1 Vishwa Karma University law journal 11.

¹¹ World Intellectual Property Organisation, *Intellectual Property and Traditional Medical Knowledge: Global Developments and Perspective* (WIPO 2023) <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-5-6-en-intellectual-property-and-traditional-medical-knowledge.pdf> accessed 09 October 2025.

¹² Ryan D Levy and Spencer Green, 'Pharmaceuticals and Biopiracy: How the AIA May Inadvertently Reduce the Misappropriation of Traditional Medicine' (2015) 23 Miami Bus L Rev 401.

rights, as their ability to maintain and practice their traditional medicinal systems is eroded.¹³

This study to address the dual Challenges of Intellectual property rights and health rights concerning the preservation of indigenous medicinal knowledge in India. It will critically examine the existing legal frameworks, such as the TRIPS agreement and India's national laws, to assess their effectiveness in protecting traditional knowledge and preventing biopiracy. The research will also explore the broader implications of these frameworks for Indigenous health rights, particularly focusing on how the commercialization of traditional medicinal knowledge impacts community access to healthcare. By proposing alternative legal and policy frameworks, this study aims to offer solutions that promote the sustainable preservation of indigenous medicinal knowledge while ensuring that the rights of indigenous community are respected and protected.

In this context, this study will highlight the need for more equitable intellectual property framework that recognize the collective ownership of traditional knowledge, promote benefit-sharing arrangements, and protect the cultural and health rights of indigenous communities. Only by addressing these challenges holistically can India ensure the preservation of its rich indigenous medicinal heritage for future generations.

1. Defining the problem: Protecting Indigenous Medicinal Knowledge and Health Rights

India's rich repository of Indigenous knowledge, deeply embedded in traditional healing system such as Ayurveda, Unani, and Siddha, is at a crossroads in the modern era.¹⁴ Despite its critical role in both healthcare and cultural identity, this knowledge is increasingly threatened by adequate legal protections and commercial exploitation.¹⁵ Indigenous, are now vulnerable to biopiracy and misappropriation, particularly by pharmaceutical companies and researchers. These entities often capitalize on traditional knowledge without seeking the consent of

¹³ WHO, 'Frequently Asked Questions on the Health and Rights of Indigenous People' (Global Plan of Action for Health of Indigenous Peoples) <https://www.who.int/initiatives/global-plan-of-action-for-health-of-indigenous-peoples/frequently-asked-questions-on-the-health-and-rights-of-indigenous-peoples> accessed 07 October 2025.

¹⁴ Ibid 2.

¹⁵ Deven McGraw and Kenneth D Mandl, 'Privacy Protections to Encourage Use of Health- Relevant Digital Data in a Learning Health System' (2021) 4 NPJ Digital Medicine 2 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7782585/> accessed 06 October 2025.

indigenous communities or establishing benefit-sharing mechanisms, depriving them of their rightful control and rewards.¹⁶

The intellectual property (IP) frameworks currently in place, such as patents and trademarks, are largely unsuitable for protecting this collective and communal knowledge. These systems are designed to safeguard individual ownership and modern innovations, which makes it difficult to apply them to ancient, community-owned knowledge that has been preserved through oral traditions.¹⁷ As a result, indigenous medicinal knowledge often falls through legal loopholes, leaving communities without the necessary recognition, protection, or control over their invaluable knowledge but also facilitates its commodification and exploitation by external actors.¹⁸

In parallel, the erosion of this knowledge poses a grave threat to health rights, particularly for indigenous groups who rely on traditional medicinal practices as their primary healthcare source. As this knowledge is commercialized and privatized under intellectual property regimes, access to traditional healthcare resource becomes restricted, marginalizing indigenous healthcare systems.¹⁹ This in turn, undermines the health sovereignty of these communities, depriving them of access to affordable, culturally appropriate healthcare. In threatening to commodify their medicinal heritage, not only is the survival of indigenous communities jeopardized, but the capacity of future generations to benefit from this heritage is also compromised.

This research aims to address the combined challenges of protecting indigenous medicinal knowledge as intellectual property and ensuring the health right of the communities that depend on this knowledge. By critically evaluating current legal framework, such as trademark under the TRIPS agreement, that impact on indigenous health rights will be assessed. Additionally, the study will propose alternative ways to preserve this invaluable knowledge sustainably and

¹⁶ Nicloe Redvers and Others, 'Indigenous Peoples: Traditional Knowledges, Climate Changes, and Health' (2023) 3(10) PLOS Global Public health <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10575522/> accessed 13 October 2025.

¹⁷ Riya, 'Protection of Traditional knowledge under Intellectual Property Rights Regime' (2020) 1(1) E-JAIRIPA 149 <https://cnlu.ac.in/storage/2022/08/10-Riya.pdf> accessed 9 October 2025.

¹⁸ Simran Kaur Khalsa, 'IP and Indigenous Communities: Protecting Traditional Knowledge and Cultural Heritage' (DePenning, 26 April 2024) <https://depenning.com/blog/ip-and-indigenous-communities-protecting-traditional-knowledge-and-cultural-heritage/> accessed 09 October 2025.

¹⁹ Joyeeta Gupta et al, A just world on a safe planet: Lancet Planetary Health-Earth Commission report on Earth-system boundaries translations, and transformations (The Lancet Planetary Health Commission 2024) <https://www.thelancet.com/action/showPdf?pii=S2542-5196%2824%2900042-1> accessed 08 October 2025.

protect the health rights of indigenous communities. Addressing these dual challenges is essential to preserving India's rich medicinal heritage and the health sovereignty of its Indigenous population.

2. Research Objectives, Scope, and Limitations

The objective of this study is to assess the effectiveness of current intellectual property rights (IPR) framework in protecting Indigenous medicinal knowledge in India and to explore their impact on the health rights of Indigenous communities. The research aims to critically analyse existing legal protections, such as those provided under the Patent Act, the Biological Diversity Act, and other relevant legislations, to determine their adequacy in safeguarding traditional medicinal practices. Additionally, the study will identify key challenges, such as biopiracy and misappropriation, that Indigenous communities face in maintaining control over their knowledge.

The study seeks to propose viable legal and policy solution to address these challenges, including potential reforms in IPR laws and the introduction of alternative protection mechanisms, such as sui generis systems or community-based approaches that align with communal nature of traditional knowledge. By examining case studies the research will offer recommendations to enhance the preservation of Indigenous medicinal knowledge and ensure that benefits derived from its use equitably shared with the communities who are its rightful custodians.

In terms of scope, the research is geographically limited to India and focuses on the field of Intellectual Property Rights as they relate to the protection of Indigenous medicinal knowledge. It will analyse the intersection of IPR with health rights, particularly within Indigenous communities. The Study does not cover non-medicinal traditional knowledge or extends to IPR issues outside the specific domain of traditional medicinal practices.

The limitation of this study lies in its exclusive focus on India's legal framework and the protection for Indigenous knowledge will not be deeply explored, and the study will not extend to sectors beyond healthcare, such as agriculture or environment management. Additionally, while the research will examine the impact on health rights, it will not delve into broader health policy issue outside the realm of traditional knowledge.

II. Review of Literature

V.K. Gupta in “**Protecting India’s Traditional Knowledge**”²⁰ aim to protect India’s traditional medicinal Knowledge from being patented without consent. He focuses on India’s traditional formulations, the global patent system, and biopiracy, with establish TKDL as a tool to prevent erroneous patents and bridge linguistic gap in patent assessment. His main purpose was to safeguard India’s rich traditional medicinal knowledge from misappropriation and misuse and also to promote the sustainable use and protection of traditional knowledge globally.

Yoonus Imran, Nalaka Wijekoon & other in ‘**Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities**’²¹ aim to explore the issue of biopiracy, particularly in the context of indigenous medicinal knowledge and its implications for health rights and intellectual property in developing countries like India. All authors encompass global cases of biopiracy, the impact of corporate patenting on indigenous knowledge, and the role of biodiversity in sustainable development, specifically focusing on Sri Lanka and India. It will examine bioprospecting practices, legal frameworks, and international protocols like the Nagoya Protocol. The purpose of their efforts to pervasive issue of biopiracy, its economic and environment consequences, and the need for fair utilization of biological resources. The research aims to purpose solutions for preserving indigenous knowledge and enhancing the socio-economic status of communities dependent on traditional practices. The author had objectives to analyse typical cases of global biopiracy and their implications for developing countries in bioprospecting, and to evaluate the role of cost-effective DNA fingerprinting technologies in bioprospecting.

Karol Gregorczuk in ‘**Legal Protection of Traditional Medicine in India**’²² focuses on the legal protection of traditional medicine in India. It explains that traditional Indian medicine, comprising system like Ayurveda, Siddha, Unani, and Sowa-Rigpa, hold significant cultural and medical importance. The article discusses the historical background, legal frameworks, and

²⁰ V.K. Gupta, ‘Protecting India’s Traditional Knowledge’ (WIPO Magazine, 2011) https://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html#:~:text=There%20are%20concerns%20that%20this,this%20knowledge%20originated%20and%20exists accessed 09 October 2025.

²¹ Yoonus Imran, Nakala Wijekoon, Lakmal Gonawala, Yu-Chung Chiang and K Ranil D De Silva, ‘Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities’ (2021) Scientific World Journal <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7910072/> accessed 06 October 2025.

²² Karol Gregorczuk, ‘Legal Protection of Traditional Medicine in India’ (2024) Cultural Heritage Law In Asia https://ejournals.eu/pliki_artykułu_czasopisma/pelny_tekst/01907950-522a-7295-ab80-3b21c54d8398/pobierz accessed 07 October 2025.

regularly efforts aimed at safeguarding this intangible cultural heritage. India has introduced legal mechanisms to regulate and protect these systems, including the Drugs and Cosmetics Act (1940), and established regulatory bodies like AYUSH. The study emphasizes the need to integrate traditional and modern medicine and enhance legal protections against biopiracy.

Riya in **‘Protection of Traditional Knowledge under intellectual Property Rights Regime’**²³ aims to explore the significance of traditional knowledge (TK) in sustainable development and its potential for preservation and protection from misappropriation. It focuses on India’s biodiversity and the role of indigenous population in preserving TK, while also examining various forms of TK across different cultures. The objective is to highlight the importance of TK in field such as medicine, agriculture, and ecology, and to advocate for legal framework to protect this knowledge. Key research question includes what constitutes traditional knowledge. The research acknowledges limitation such as challenges in documenting and quantifying protective TK, variations in cultural practices, and difficulties in implementing protectives measures. Further the purpose of the study is to emphasize the need for effective legal protection of traditional knowledge, promote its sustainable use, and encourage indigenous communities to leverage TK for their development.

Mohini Sharma in **“Concerning Aspects of Traditional Knowledge Related to Health, Human Rights And IPR”**²⁴ aims to analyse the influence of traditional Knowledge on healthcare accessibility and the significance of intellectual property rights (IPR) in protecting this knowledge. It discusses the relevance of traditional medicine, particularly Ayurveda, in public health, addressing the challenges it faces and the interplay between culture, policy, economics. The objective includes examining barriers to healthcare access, especially for marginalized groups, especially for marginalized group, assessing the role of the IPR in safeguarding traditional knowledge and proposing strategies to improve care accessibility for vulnerable population. The study advocates for mainstreaming traditional medicine within healthcare systems emphasizing IPR’s importance in protecting traditional knowledge and the need for enhance healthcare accessibility for marginalized group, particularly children and

²³ Riya, ‘Protection of Traditional knowledge under Intellectual Property Rights Regime’ (2020) 1(1) E-JAIRIPA 149 <https://cnlu.ac.in/storage/2022/08/10-Riya.pdf> accessed 9 October 2025.

²⁴ Mohini Sharma, ‘Concerning Aspects of Traditional Knowledge Related to Health, Human Rights and IPR’ (2016) https://www.researchgate.net/publication/312947234_Concerning_aspects_of_traditional_knowledge_related_to_health_human_rights_and_IPR accessed 08 October 2025.

pregnant women.

Upon reviewing the relevant literature on the Indigenous medicinal knowledge, traditional practices, and health rights, several key research gaps have been identified. Firstly, the existing intellectual property rights frameworks in protecting Indigenous medicinal knowledge, but there is little focus on how these legal shortfalls affect the health rights of Indigenous communities. While bio-piracy and misappropriation are common themes, few studies explore the direct relationship between the erosion of traditional knowledge and the loss of healthcare access in Indigenous communities. Additionally, much of the literature lacks empirical evidence from Indigenous perspective, focusing more on legal analysis than the practical, lived consequences of losing traditional medicinal practices. Furthermore, although many studies acknowledge the inadequacy of current IPR protections, there is insufficient discussion on alternative legal framework that could provide better protection aligned with the communal nature of indigenous knowledge.

The present study, being doctrinal legal research, will address these gaps by providing a comprehensive analysis of the Indian Legal frameworks i.e. The Patent Act, 1970 & The Biological Diversity Act, 2002 and their impact on both the protection of indigenous medicinal knowledge and the health rights of Indigenous communities. By focusing exclusively on the legal aspect and proposing alternative legal mechanisms, this study will contribute to the scholarly discourse without fieldwork or scientific analysis. The doctrinal nature of the research will allow for an in-depth examination of existing laws and recommendations for reform, aiming to fill the gap in understanding how legal frameworks can be better aligned with the preservation of indigenous medicinal knowledge and the protection of health rights.

III. Methodology

This study uses a doctrinal legal research approach to assess how the protection of Indigenous medicinal knowledge in India impacts health rights. The methodology involves a comprehensive legal analysis of the Patent Act, 1970 and the Biological Diversity Act, 2002, both of which are used to protect Indigenous medicinal knowledge, is undertaken to evaluate their effectiveness. This study also highlights medicinal knowledge, is undertaken to evaluate their effectiveness. This study also highlights instances of biopiracy and misappropriation to identify research gaps in the legal framework and challenges faced. Additionally, a comparative analysis of the international intellectual property framework and challenges faced.

Additionally, a comparative analysis of the international intellectual property framework, such as TRIPS, will be conducted to examine how its approach differs from India's legal mechanisms. An in-depth review of scholarly articles, reports and legal commentaries on indigenous medicinal knowledge protection and health rights will inform the literature review. Government policies and initiatives for the protection of traditional knowledge, including the Traditional Knowledge Digital Library (TKDL), will also be examined as part of this study. This approach is grounded in the critical interpretation and application of existing laws to Indigenous medicinal knowledge protection. The study will conclude with recommendations for legal reforms and other protective mechanisms to address the communal nature of indigenous knowledge and safeguard health rights based on the findings.

IV. Findings

1. Comparative Analysis of International and Indian Legal Frameworks for Protecting Traditional Medicinal Knowledge

The protection of traditional medicinal knowledge has emerged as a critical global issue, particularly for biodiversity-rich countries like India. This analysis compares the international intellectual property framework, primarily the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, with India's legal mechanisms for safeguarding traditional knowledge. Although the TRIPS Agreement, establishes a global standard for intellectual property rights, has faced criticism for its narrow scope in addressing the unique nature of traditional knowledge. **Article 27 (3) (b) of TRIPS** mandates member countries to protect plant varieties through patents or an effective sui-generis system. However, this provision has sparked controversy due to its failure to explicitly recognize traditional knowledge or ensure benefit-sharing with indigenous communities.

India, in response to these challenges, has developed a comprehensive legal approach to protect its rich traditional medicinal knowledge:

1. **The Biological Diversity Act, 2002 (BDA)** forms the cornerstone of India's efforts to conserve biodiversity and associated traditional knowledge. The BDA creates a three-tier structure comprising the National Biodiversity Authority, State Biodiversity Boards, and local Biodiversity Management Committees. This framework aims to regulate access to biological resources and associated knowledge, ensuring equitable

benefit-sharing with local communities. Notably, the Act requires prior informed consent from local bodies before accessing traditional knowledge, a provision absent in the TRIPS Agreement.

2. **The Patents Act, 1970**, amended in 2005, includes specific provisions to combat biopiracy and misappropriation of traditional knowledge. **Section 3(p)** of the Act excludes traditional knowledge from patentability, while **Section 25(1)(k)** allows for opposition to patent applications based on prior traditional knowledge. These provisions exceed TRIPS requirements and showcase India's proactive stance in protecting its traditional knowledge within the patent system.
3. **The Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act)** serves as a sui generis system for plant variety protection, as required by TRIPS. However, it goes beyond TRIPS requirements by recognizing farmers' rights and providing for benefit-sharing. The Act acknowledges the crucial role of farmers in conserving, improving, and making available plant genetic resources, a recognition absent in TRIPS.
4. **The Geographical Indications of Goods (Registration and Protection) Act, 1999** offers another layer of protection for traditional knowledge associated with specific geographical regions. This Act has successfully protected traditional medicinal products like Darjeeling Tea and Kangra Tea, linking them to their geographical origins and associated traditional practices.
5. **The Forest Rights Act, 2006** recognizes the rights of forest-dwelling communities to access and use minor forest produce, including medicinal plants. While not directly related to intellectual property, this Act plays a vital role in preserving the traditional lifestyles and knowledge systems of indigenous communities.

India's approach, as exemplified by these laws, demonstrates a more holistic and community-centric approach to protecting traditional knowledge compared to the TRIPS framework. While TRIPS focuses primarily on individual ownership and commercial exploitation of intellectual property, India's laws attempt to balance protection with access and benefit-sharing.

In **Divya Pharmacy v. Union of India**,²⁵ the Uttarakhand High Court upheld the constitutional validity of the Biological Diversity Act and affirmed the requirement for Indian Companies to seek approval from the State Biodiversity Board before accessing biological resource for commercial utilization. The decision strengthened the implementation of benefit-sharing provisions, a concept not explicit mandated in TRIPS.

In 1995, the **Turmeric Case (*Curcuma Linga Linn*)**²⁶, where two Indian expats at the University of Mississippi Medical Centre were granted a US Patent for using turmeric to heal wounds. However, turmeric has been a staple in Indian culture for centuries, not only as a spice but also as a remedy for burns and wounds. The Indian government contested the patent, arguing that this use was not novel but part of India's long standing traditional knowledge. They provided evidence, including ancient Sanskrit texts and a 1953 study from the journal of the Indian Medical Association, demonstrating turmeric's established medicinal use. Despite an appeal from the patent holders, the US Patent and Trademark Office (USPTO) sided with the Indian government, invalidating the patent in 1997. The ruling confirmed that turmeric's medicinal properties were already well-known in India, making the patent invalid due to lack of originality. This Landmark decision was the first successful challenge of patent based on Indian traditional knowledge, marking a significant victory in the fight against biopiracy.²⁷

Similarly, in the **Neem Case**²⁸ (*Azadirachta Indica*) symbolise the challenges and successes in combating biopiracy, also was a significant legal battle between Indian and a U.S. corporation over the patenting of the Neem tree, a patent long used in Indian traditional medicine. In the 1990s, the European Patent Office (EPO) granted a patent to W.R. Grace, a U.S. company for a method using Neem oil to control fungi on plants. However, Neem's medicinal and pesticidal has been widely known and used in India for centuries. When the patent was granted in 1994, it sparked out rage in India. Many saw it as an attempt to misappropriation India's traditional knowledge for commercial purpose. Activists and the India government argued that the patent was unjust as Neem's uses were not a new discovery but part of country's long-established practices. India took the case to the EPO, challenging the

²⁵ 2018 SCC Online Utt 1035.

²⁶ *Turmeric Case (Judgement)* [1997] U.S., Patent No. 5401, 504.

²⁷ Quang, V. L. (2021) *How Did India Win in the Legal Battle Against Biopiracy Regarding Basmati Hybrid Rice Variety Patented by the USPTO and Valuable Lesson for Vietnam*, Lexology. Bross & Partners. Available at: <https://www.lexology.com/library/detail.aspx?g=3b46692a-8b13-416a-b35d-f766f69a52e2> (Accessed: 20 October 2025).

²⁸ *Neem Patent Case (Judgement)* [2001], U.S. Patent No. 5663484 A

patent on the ground that the violated their traditional knowledge. After a prolonged legal struggle, the EPO revoked the patent in 2000, acknowledging that Neem's fungicidal properties were already well-known and that W.R. Grace's patent lacked a genuine invention. This case became a landmark victory against the exploitation of traditional knowledge and biopiracy.

The **Basmati Rice Case (Oryza Sativa Linn.)**²⁹ in the Late 1990s, where RiceTec Inc. attempted to patent basmati rice lines and grains, led to India's development of the Geographical Indication Act. While not directly related to medicinal knowledge, this case demonstrated the need for protecting traditional agricultural products with cultural significance.

Case Study	Impact on Health Right	Enforcement Challenges
Kani Tribe and Arogyapacha Plant	Positive: Recognition of traditional knowledge, financial benefits. Negative: Internal conflicts over benefit distribution, equitable benefit distribution.	-Equitable benefit distribution -Balancing commercial and traditional interests
Neem Patent Revocation	Positive: Prevented monopolization, ensured access. Negative: Resource-intensive legal battle.	- Lack of proactive biopiracy prevention. - Need for better TK documentation.
Yoga as Traditional Knowledge	Positive: Prevented commercialization of traditional practices. Negative: Concerns about cultural appropriation	- Defining boundaries of traditional knowledge - Balancing protection with global adaptation
Hoodia Cactus Case	Positive: Eventually led to benefit-sharing agreement. Negative: Initial exclusion of indigenous community.	- Ensuring informed consent - Addressing power imbalances

²⁹ *India-US Basmati Rice dispute*, [2001], U.S. Patent No 5663484 A

Turmeric Patent Case	Positive: Prevented monopolization of common medicine Negative: Highlighted vulnerability of traditional remedies	- Burden of proof on TK holders - Need for proactive prevention measures
Forest Rights Act Implementation	Positive: Improved access to medicinal plants in some areas Negative: Inconsistent implementation across regions	- Balancing conservation with traditional rights - Overcoming bureaucratic hurdles
TKDL Impact	Positive: Prevented patents restricting access to traditional medicines Negative: Concerns about public disclosure of sensitive knowledge	- Ensuring comprehensive documentation - Integrating TKDL in international patent processes

These cases illustrate how India's legal framework, while more comprehensive than international standards in protecting traditional knowledge, still faces challenges in implementation and enforcement. The creation of the TKDL and the active role Indian Institutions in challenging patents internationally demonstrate a proactive approach to protecting traditional knowledge that goes beyond the reactive measure suggested by TRIPS.

Despite progress in protecting traditional knowledge, challenges remain in the global and national frameworks. The TRIPS Agreement emphasizes individual, time-limited rights, which conflict with the communal and intergenerational nature of traditional knowledge. In India, laws like the Biological Diversity Act and Forest Rights Act aim to protect traditional knowledge, but their enforcement faces hurdles, particularly in ensuring fair benefit-sharing and preventing unauthorised access.

At the international level, there is still no binding instrument specifically for traditional knowledge protection, though efforts are ongoing at the World Intellectual Property Organisational (WIPO). In contrast, India's legal framework provides a more comprehensive model that exceeds TRIPS' requirements. It acknowledges the role of customary laws in protecting traditional knowledge, a factor largely overlooked in global agreements. India's approach integrates sui generis systems, patent law amendments, and community rights, offering a holistic model to safeguard traditional medicinal knowledge. This not only prevents

misuse but also promotes and preserves these knowledge systems, recognition their cultural and economic importance to indigenous communities. While India's framework offers valuable insights, its effectiveness in practice, especially in terms of health rights and access to traditional medicines, requires further research and analysis to ensure the laws achieve their intended impact.

2. Findings through in-depth Literature Review on Indigenous Medicinal Knowledge Protection and Health Rights

The comprehensive literature review conducted for this study reveals several key findings regarding the protection of Indigenous medicinal knowledge and its impact on health rights:

Legal Framework Inadequacies: Scholars consistently highlight the inadequacy of current intellectual property rights (IPR) frameworks in protecting Indigenous medicinal knowledge. The conventional IPR system, designed primarily for individual innovations, fails to accommodate the communal and intergenerational nature of traditional knowledge. This misalignment leaves Indigenous medicinal knowledge vulnerable to misappropriation and exploitation. As Duffield argues, "The very nature of traditional knowledge – collective, evolving, and often uncodified – makes it an awkward fit with conventional IP systems designed to grant exclusive rights to individuals or companies for specific inventions."³⁰

Biopiracy and Misappropriation: Numerous studies document cases of biopiracy, where traditional medicinal knowledge is patented by external entities without proper attribution or compensation to Indigenous communities. The turmeric and neem cases in India are frequently cited as examples of this issue. These instances underscore the urgent need for more robust legal protections tailored to the unique characteristics of traditional knowledge. As Shiva notes, "Biopiracy is the Columbian 'discovery' 500 years after Columbus. Biopiracy is the unauthorised and uncompensated taking of biological resources."³¹

Health Rights Implications: Research indicates a strong correlation between the erosion of traditional medicinal knowledge and the deterioration of health rights in Indigenous communities. As traditional practices are commercialized or restricted due to IPR issues, many Indigenous groups lose access to their primary healthcare resources. This not only violates their

³⁰ Graham Dutfield, 'TRIPs-Related Aspects of Traditional Knowledge' (2001) 33 Case W Res J Int'l L 233, 237.

³¹ Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press 1997) 5.

right to health but also threatens their cultural integrity. Oguamanam observes, "The loss of traditional medicinal knowledge is not just a loss of potential pharmaceutical discoveries, but a direct threat to the health sovereignty of Indigenous peoples."³²

Community Perspectives: Studies incorporating Indigenous voices reveal a deep concern among communities about the loss of control over their medicinal knowledge. Many express frustrations with the current legal frameworks, which they view as incompatible with their worldviews and traditional practices. There is a strong call for greater autonomy in managing and protecting their knowledge. As one Indigenous leader stated in a study by Drahos, "Our knowledge is not a commodity to be owned, but a responsibility to be safeguarded for future generations."³³

Alternative Protection Mechanisms: Scholars propose various alternative approaches to protect Indigenous medicinal knowledge, including:

- Sui generis systems tailored to the specific needs of traditional knowledge
- Community protocols for managing access and benefit-sharing
- Recognition of customary laws in national legal frameworks

These alternatives aim to provide more culturally appropriate and effective protection mechanisms. *Tobin* argues, "The development of sui generis systems offers a promising path to reconcile the protection of traditional knowledge with the cultural and spiritual values of Indigenous communities."³⁴

International Agreements and National Laws: The literature review reveals a complex interplay between international agreements like TRIPS and national laws. While TRIPS sets global standards for IPR, it has been criticized for its limitations in addressing traditional knowledge. In response, countries like India have developed national laws (e.g., the Biological Diversity Act, 2002) to fill these gaps. However, the effectiveness of these national measures

³² Chidi Oguamanam, 'Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge' (2004) 11 Ind J Global Legal Stud 135, 159.

³³ Peter Drahos, *Intellectual Property, Indigenous People and their Knowledge* (Cambridge University Press 2014) 102.

³⁴ Brendan Tobin, *Indigenous Peoples, Customary Law and Human Rights – Why Living Law Matters* (Routledge 2014) 178.

in the global context remains a subject of debate. As Mgbeoji notes, "The tension between international IP regimes and national efforts to protect traditional knowledge highlights the need for a more harmonized global approach."³⁵

Documentation Dilemma: Scholars discuss the double-edged nature of documenting traditional knowledge. While documentation can help prevent erroneous patents and preserve knowledge, it also raises concerns about the potential misuse of documented information and the loss of secrecy in sacred knowledge. Okediji observes, "The act of documenting traditional knowledge, while potentially protective, can also make it more vulnerable to exploitation if not carefully managed."³⁶

Benefit-Sharing Challenges: Research highlights the difficulties in implementing fair and equitable benefit-sharing mechanisms. Even when legal provisions exist, ensuring that benefits reach the rightful knowledge holders remains a significant challenge. As Wynberg points out, "The concept of benefit-sharing, while noble in intent, often falls short in practice due to power imbalances and implementation challenges."³⁷

Integration with Modern Healthcare: Some studies advocate for the integration of traditional medicinal practices into mainstream healthcare systems. This approach is seen as a way to both preserve traditional knowledge and improve healthcare access for Indigenous communities. However, concerns about the potential for exploitation and cultural appropriation in this process are also noted. Bodeker argues, "Integration must be done on the terms of Indigenous communities, respecting their knowledge systems and cultural contexts."³⁸

Capacity Building Needs: Many researchers emphasize the need for capacity building within Indigenous communities to enable them to better navigate complex IPR systems and assert their rights. This includes legal education, documentation skills, and negotiation capabilities. As Drahos suggests, "Empowering Indigenous communities with the tools to protect their knowledge is as crucial as developing legal frameworks."³⁹

³⁵ Ikechi Mgbeoji, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (UBC Press 2006) 201.

³⁶ Ruth L Okediji, 'Traditional Knowledge and the Public Domain' (2018) CIGI Papers No. 176, 12.

³⁷ Rachel Wynberg, 'Rhetoric, Realism and Benefit-Sharing' (2004) 7 J World Intell Prop 851, 860.

³⁸ Gerard Bodeker, 'Integrating Traditional and Complementary Medicine into National Health Care' (2001) 2 J Altern Complement Med 203, 20.

³⁹ Peter Drahos, 'Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?' (2000) 22 Eur Intell Prop Rev 245, 2

The literature review reveals a complex landscape where legal, cultural, economic, and health considerations intersect. While there is a growing recognition of the importance of protecting Indigenous medicinal knowledge, significant challenges remain in developing and implementing effective protection mechanisms that respect Indigenous rights and worldviews while operating within the global IPR system.

3. Examination of Government Policies and Initiatives Related to Traditional Knowledge Protection

The examination of government policies and initiatives related to traditional knowledge protection, with a particular focus on the Traditional Knowledge Digital Library (TKDL), reveals several key findings:

A. Traditional Knowledge Digital Library (TKDL):

The TKDL, initiated by the Indian government, stands out as a pioneering effort to protect traditional knowledge from misappropriation. Key findings include:

- i. Comprehensive Documentation:* The TKDL contains over 3.9 million pages of formatted information on traditional medicinal formulations, making it one of the most extensive databases of its kind globally. As noted by Gupta, "The TKDL represents a monumental effort to bridge the linguistic and format divide that often leads to erroneous patent grants on traditional knowledge."⁴⁰
- ii. Multilingual Approach:* The database is available in multiple languages (English, German, French, Japanese, Spanish), enhancing its accessibility to patent examiners worldwide. This multilingual approach is crucial in preventing biopiracy, as it allows examiners to understand and recognize prior art in traditional knowledge across linguistic barriers.
- iii. Patent Examination Tool:* The TKDL has been effective in preventing erroneous patents. Several patent applications in various countries have been either withdrawn or rejected based on prior art evidence from the TKDL. As reported by the World

⁴⁰ V.K. Gupta, 'Protecting India's Traditional Knowledge' (2011) 16 WIPO Magazine 5,7.

Intellectual Property Organization, "The TKDL has successfully challenged over 200 patent applications related to Indian traditional knowledge."⁴¹

- iv. **Challenges in Implementation:** Despite its success, the TKDL faces challenges such as keeping the database updated, ensuring comprehensive coverage, and balancing openness with the need to protect sensitive information. *Oguamanam* observes, "While the TKDL is a significant step forward, it grapples with the dynamic nature of traditional knowledge and the need for continuous updating."⁴²

B. Policy Initiatives:

- i. **Several policy initiatives complement the legal framework:** National Biodiversity Strategy and Action Plan: This plan includes strategies for the conservation and sustainable use of biological diversity, including associated traditional knowledge. However, critics like Gadgil argue, "The plan, while comprehensive on paper, lacks effective mechanisms for on-ground implementation, particularly in involving local communities."⁴³
- ii. **AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy) Ministry:** The creation of a separate ministry for traditional medicine systems demonstrates the government's commitment to preserving and promoting these knowledge systems. As Patwardhan notes, "The AYUSH Ministry has elevated the status of traditional medicine, but challenges remain in integrating these systems with mainstream healthcare."
- iii. **Biodiversity Heritage Sites:** The government has provisions for declaring areas rich in biodiversity and associated traditional knowledge as Biodiversity Heritage Sites, providing them with special protection. However, Kothari points out, "The implementation of this provision has been slow, with only a handful of sites declared, limiting its potential impact."

⁴¹ World Intellectual Property Organization, 'Protecting India's Traditional Knowledge' (WIPO Magazine, June 2011) https://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html accessed 15 October 2024

⁴² Chidi Oguamanam, 'Tiered or Differentiated Approach to Traditional Knowledge and Traditional Cultural Expressions: The Evolution of a Concept' (2018) 11 WIPO J 67, 75.

⁴³ Madhav Gadgil, 'Ecology is for the people: A Methodology Manual for People's Biodiversity Register' (2006) Centre for Ecological Science, Indian Institute of Science, 23.

- iv. Convention on Biological Diversity (CBD):** India has been instrumental in pushing for the implementation of the Nagoya Protocol on Access and Benefit-sharing. However, Nijar notes, "While India has been proactive in CBD forums, translating international commitments into domestic action remains a challenge."

However, while India has made significant strides in developing policies and initiatives to protect traditional knowledge, particularly through the TKDL and comprehensive legal frameworks, challenges remain in implementation, enforcement, and ensuring that these measures effectively benefit the traditional knowledge holders. The government's multifaceted approach, combining legal, policy, and technological measures, reflects the complex nature of protecting traditional knowledge in the modern context. However, continued efforts are needed to address the gaps between policy formulation and ground-level implementation to ensure the effective preservation and protection of India's rich traditional medicinal knowledge.

V. Discussion

This study finds a complicated relationship between inadequate legal protection and the maintenance of indigenous medicinal knowledge in India. The researcher has synthesised these findings and the extant literature to offer a more nuanced analysis of the challenges and opportunities.

A. Inadequacy of Current Legal Framework

The current IPR framework primarily designed for individual innovations, fails to adequately protect the communal nature of Indigenous medicinal knowledge. This inadequacy manifests in several ways:

- 1. Misalignment with Traditional Knowledge Systems:** The IPR system's focus on individual ownership and time-limited protection clashes fundamentally with the communal, intergenerational nature of indigenous knowledge. As Dutfield argues, "The very nature of traditional knowledge.....collective, evolving, and often uncodified.....makes it an awkward fit with conventional IP systems designed to grant exclusive rights to individuals or companies for specific invention"⁴⁴

⁴⁴ Graham Dutfield, 'TRIPs-Related Aspect of Traditional Knowledge' (2001) 33 Case W Res J Int'l L 233, 237.

2. ***Vulnerability to Biopiracy:*** Many cases of biopiracy, the patenting of external entities without proper attribution or compensation of traditional medicinal knowledge, have gone unnoticed because of lack of appropriate legal protections. The turmeric and neem cases in India exemplify this issue, underscoring the urgent need for more robust legal protections tailored to the unique characteristics of traditional knowledge.⁴⁵
3. ***Impact on Health Rights:*** The IPR issues of traditional medicine have led to a worsening of health rights in Indigenous communities since they came to be commercialised and restricted. As *Oguamanam* observes, “the loss of traditional medicinal knowledge is not just loss of potential pharmaceutical discoveries, but a direct threat to the health sovereignty of Indigenous peoples”.

B. Community Perspective and Alternative Protection Mechanisms

The study's call for change, for greater autonomy for Indigenous communities to manage and protect their knowledge, is strong. This aligns with Drahos' finding, where Indigenous leaders emphasize that “Our knowledge is not a commodity to be owned, but a responsibility to be safeguarded for future generations.”⁴⁶

This perspective underscores the need for alternative protection mechanisms, such as:

1. ***Sui Generis Systems:*** Developing unique legal framework tailored to the specific needs of traditional knowledge protection. As Tobin argues, “The development of sui generis system offers a promising path to reconcile the protection of traditional knowledge with the cultural and spiritual values of Indigenous communities.”
2. ***Recognition of Customary Laws:*** Incorporating traditional governance systems into the legal framework for protecting medicinal knowledge. This approach acknowledges the sophisticated traditional mechanisms for knowledge management that have sustained these practices for generations.

Conclusion

This study has examined the complex challenges surrounding the protection of Indigenous

⁴⁵ Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press 1997) 5.

⁴⁶ Peter Drahos, *Intellectual Property, Indigenous People and their knowledge* (Cambridge University Press 2014) 102.

medicinal knowledge in India, focusing on the inadequacies of the current legal framework and their impact on Indigenous health rights. The research underscores the critical importance of preserving Indigenous medicinal knowledge, not only as a valuable healthcare resource but also as an integral part of cultural identity. The current IPR framework, designed primarily for individual innovations, fails to adequately protect the communal and intergenerational nature of Indigenous knowledge. This inadequacy has led to numerous cases of misappropriation and unauthorised commercialization of traditional medicines, often without proper attribution of benefit sharing with Indigenous communities.

The study also shows the depth of the impact these legal defects have on the exercise of Indigenous health rights. The patenting of traditional medicines, commercialisation of medicines deriving from traditional medicines and the global nature of intellectual property regimes which prioritize commercial interests over the rights of traditional medicine holders all contribute to making the situation worse for many Indigenous communities who have limited access to their medicinal resources for consequent enforcement of their human rights, including the right to culturally appropriate healthcare.

The research also identifies obstacles to the implementation of effective protection mechanisms, such as the problem of how to document oral traditions without compromising their sacred or secret nature; and the problems of asserting rights across different legal jurisdictions.

In sum, a lot of progress has been made in recognizing the importance of protecting Indigenous medicinal knowledge, but very few concrete steps have been taken to develop and implement effective protection mechanisms that honour Indigenous rights and worldviews as well as international IPR law. This means the world must first balance preserving traditional knowledge, community rights and innovation in healthcare.

Recommendations

Drawing from the detailed discussion of the issues affecting Indigenous medicinal knowledge protection and health rights, this research provides a systematic approach to change. The recommendations call for shift whose emphasis is on a shift from conventional IPR systems and, towards sui generis system that takes cognizance of traditional knowledge's communal and intergenerational attributes. Such approach requires new special provisions on traditional

knowledge incorporation into the existing legal systems alongside enhancement of prior informed consent and just benefit-sharing mechanisms.

Community engagement structure is well emphasized in the research, calling for enhanced capacity development programs for the enhancement of Indigenous communities in the protection of their own assets. Initiating of these kinds of programs include promoting procedures and regulations for community participation in external affairs (in terms of other jurisdiction or dealing with any entity or person of another jurisdiction) and establishing mechanisms to ensure the inclusion of Indigenous individuals in decision making processes, when it comes to the any infringement, irregularity or breach of any right of respective individual. The work also presents issues of documentation and suggests how to deal with them without compromising the protection of certain knowledge while preserving the cultural contexts of the traditional activities. The change in legal frameworks, moving beyond conventional IPR systems to develop sui generis mechanism that align with the communal and intergenerational nature of traditional knowledge. This approach necessitates amending existing laws to incorporate specific provisions for traditional knowledge protection, while simultaneously strengthening mechanisms for prior informed consent and equitable benefit-sharing.

The research underscores the critical importance of community empowerment, advocating for capacity-building programs that enable Indigenous communities to actively manage and protect their knowledge. This include supporting the development of community protocols for engagement with external entities, ensuring that Indigenous voices are central in decision-making processes. The study also addresses the documentation dilemma, recommending culturally sensitive approaches to knowledge preservation that balance the need for protection with respect for sacred and secret aspects of traditional practices. This requires creation of separate, closed databases, which do not allow re-use of records by unauthorised parties, as well as maintaining cultural sensitivity.

At the international level, the results imply a coordinated attempt to change the current rules of international IPRs and promote the frameworks, corresponding to the Indigenous worldview, to enhance cooperation in addressing biopiracy issues. The study also finds out the possibility of shared complementary system and policy by adopting traditional and modern health systems, policies that should be put in place to encourage the research and validation of traditional

medicines in their cultural practices.

Education and awareness become important features where suggestions were made to produce a specific awareness-raising programs on the importance of indigenous medical knowledge to legal personals and policy makers and to the general populace. More predominantly, the study stress on raising political awareness and applying Indigenous customary laws as the constituents of the national law that can contribute to the exercise of traditional governance systems in protecting knowledge.

In conclusion, the recommendations specify the need for effective monitoring and compliance measures together with legal assistance for Indigenous people. The goal of this multifaceted approach is to establish a fairer and definitely more efficient system for the protection of Indigenous medicinal knowledge so that these invaluable practices can be kept under protection while at the same time empowering Indigenous people to make of their knowledge a contribution to worldwide health solutions. The proposed measure embodies a sophisticated perspective of the relationships between culture, health, and intellectual property in relation to Indigenous peoples' knowledge about plants used in Traditional Medicines.