

Legal Framework for Access and Benefit Sharing (ABS) of Traditional Knowledge Associated with Biological Resources in India: Challenges, Biopiracy and Sustainable Development Perspectives

Nandita Patil¹

¹ Department of Law, Dr. Babasaheb Ambedkar Marathwada University, Chhatrapati Sambhajnagar – 431004, Maharashtra, India.

² Mechanical Engineering Department, Government College of Engineering, Chhatrapati Sambhajnagar – 431005, Maharashtra, India.

Email: nandinips.patil21@gmail.com

ORCID: 0009-0008-7425-8115

Corresponding Author:

Nandita Patil

Email: nandinips.patil21@gmail.com

ORCID: 0009-0008-7425-8115

Abstract

Access and Benefit Sharing (ABS) is a legal mechanism aimed at ensuring fair and equitable sharing of benefits arising from the use of biological resources and traditional knowledge. Indigenous and local communities have preserved biodiversity and traditional medicinal knowledge for generations, but commercialization of these resources has often led to exploitation and biopiracy. International instruments such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol recognize sovereign rights over biological resources and emphasize Prior Informed Consent (PIC) and equitable benefit sharing.

This paper critically examines the Indian legal framework governing ABS and protection of traditional knowledge associated with biological resources. It analyzes important legislations including the Biological Diversity Act, 2002, the Protection of Plant Varieties and Farmers' Rights Act, 2001, and relevant provisions of the Patent Act, 1970. The study also discusses major biopiracy cases such as Neem, Turmeric, and Basmati, along with ABS models like the Jeevani case. The paper highlights challenges relating to implementation, participation of indigenous communities, intellectual property rights, and biodiversity conservation. It concludes with suggestions for strengthening community participation, preventing biopiracy, and ensuring sustainable development through effective ABS mechanisms.

Keywords: Access and Benefit Sharing, Traditional Knowledge, Biodiversity, Biopiracy, Intellectual Property Rights, CBD, Nagoya Protocol, TKDL.....

Introduction

Biodiversity and traditional knowledge are priceless assets for social, economic, scientific and cultural development of humanity. Biological resources and associated traditional knowledge have played a crucial role in agriculture, medicine, food security, environmental sustainability, and scientific innovation for centuries. Inevitably, indigenous and local communities around the globe have maintained and safeguarded biodiversity through traditional approaches of biodiversity conservation and indigenous knowledge systems passed down from generation to generation (Barpujari & Sarma, 2017). Traditional medicinal knowledge is the base of several health care systems around the world such as Ayurveda, Siddha, Unani and folk medicine (Ansari, 2019).

The vast value of biological resources and traditional knowledge has emerged due to the fast advancement of biotechnology, pharmaceutical industries, and genetic studies. Medicinal plants, microorganisms, and genetic materials are being used more and more by researchers and multinational industries for creating medicines, cosmetics, agriculture technologies, and nutraceuticals (Bajpai & Sikarwar, 2024).

Along with this, use of biological resources for economic purposes has raised significant issues such as exploitation of indigenous knowledge, unauthorised access to genetic resources and biopiracy. The unauthorized

use of biological resources and TK without the prior informed consent or appropriate remuneration of indigenous and local people who have held these knowledge for centuries is called 'biopiracy' (Bond & Scott, 2020).

The issue of biopiracy was highlighted by a number of international controversies relating to traditional medicinal knowledge and biological resources from developing nations for which patents have been applied. The cases of turmeric, neem and basmati rice in India are significant examples of attempts by foreign players to claim intellectual property rights over traditional knowledge and resources of India (José & Manchikanti, 2021). These events brought the shortcomings of traditional IP regimes in the protection of TK and equitable benefit sharing in light of its use to the fore. Therefore, the international community acknowledged the need for development of a legal instrument to address access to genetic resources and benefit sharing.

The Convention on Biological Diversity (CBD), which was negotiated in 1992, is an internationally recognized document that provides for the conservation of biodiversity, sustainable use of biological resources and fair and equitable benefit-sharing arising from the utilization of genetic resources. The CBD recognizes the sovereign rights of states over their biological resources and provides that access to such resources should be subject to Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) (Reichman, 2019).

Later, the Nagoya Protocol on Access and Benefit Sharing (2010) reinforced the ABS, developing an elaborate legal structure to define the obligations and rights to share benefits and compliance (Bajpai & Dixit, 2025). The Nagoya Protocol places a strong focus on considering the participation of indigenous and local communities, and aims at fostering fair sharing of benefits arising from the utilization of biological resources and the traditional knowledge associated with them.

However, a number of legal and practical issues remain in the way of national and international implementation of ABS. There is one major challenge with respect to the increasing use of Digital Sequence Information (DSI) on genetic resources. New developments in technology allow researchers to store and access genetic information digitally – without access to biological samples, complicating the present ABS frameworks (Akpoviri et al., 2023). The lack of international standards on DSI has sparked discussions about the obligations for benefit sharing and digital biopiracy (Kharb, 2021). In a similar way, there is growing concern about the circumvention of ABS obligations under the Nagoya Protocol in relation to the digitization of biological information and genetic databases (Smyth et al., 2020). India is known as one of the most mega-diverse countries in the world with rich biodiversity and traditional medicinal knowledge.

To address concerns about biopiracy and misuse of TK, India came up with the Biological Diversity Act, 2002 implementing the provisions of the CBD and laying a legal framework for conserving biodiversity and equitable benefit sharing. The Act introduces the concepts of institutional mechanism including National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and Biodiversity Management Committees (BMCs) for access to biological resources and associated TK. India has also introduced the Protection of Plant Varieties and Farmers' Rights Act 2001, and the following disclosure requirements in the Patent Act, 1970, to prevent wrongful patenting of traditional knowledge and biological resources. Among the important steps that have been taken by India is the creation of the Traditional Knowledge Digital Library (TKDL) to record traditional medicine formulations of Ayurveda, Siddha, Unani and Yoga in digital format.

The TKDL is also crucial to protect from Biopiracy by allowing the patent officers across the globe to identify the prior art and to reject the invalid patent claims filed (Ansari, 2019). In Fredriksson's (2021) view, the TKDL has revolutionised the process of patent examination around the world by incorporating the traditional knowledge into the modern intellectual property system. The initiative of TKDL as a facilitator for the Patent System has added even more weight to the efforts of protecting IMED (Yadav & V., 2024). While India has put in place a relatively robust legal regime for ABS and TK protection, there are several outstanding problems. Issues of effective involvement of indigenous communities, implementation of benefit-sharing agreements, conservation of biodiversity, digital sequence information, and harmonisation between IP rights and biodiversity laws still remain to be addressed (Trivedi, 2024). Furthermore, recent events around the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge have added to the debate about international ABS governance and IP protection (Lee & Chang, 2024).

In this regard, the current research has critically looked into the policy and legal framework of Access and Benefit Sharing in India, particularly the traditional knowledge surrounding biological resources and IPRs. The study examines the international legal instruments, Indian biodiversity laws, ABS models, ABS biopiracy cases, and

challenges in the digital era. It also assesses the effectiveness of the current legal instruments, and recommends changes to the legal framework to ensure fair and equitable benefit sharing, the protection of indigenous rights, the prevention of biopiracy, and the promotion of sustainable development.

Table 1: India, TKDL, and Traditional Medical Knowledge

Aspect	Main function	Key tensions	Citations
TKDL	Defensive tool to block patents on known traditional knowledge	Risk of decontextualization; calls to commercialize access and share revenues with communities	(Trivedi, 2024; José & Manchikanti, 2021; Fredriksson, 2021; Yadav & Vibha, 2024; Ansari, 2019)
ABS laws (Biological Diversity Act etc.)	Regulate access to genetic resources / TK and mandate benefit sharing	Biopiracy, weak benefit flows to indigenous groups, conflicts with research access	(Vincent, 2024; José & Manchikanti, 2021; Bajpai & Sikarwar, 2024; Barpujari & Sarma, 2017)

2. Indian Legal Framework on ABS and Traditional Knowledge

India is known as one of the mega diversified countries with high diversity of flora and fauna or traditional knowledge of medicinal plants, agriculture, forests and indigenous healthcare system. The traditional knowledge in India is strongly associated with Ayurveda, Siddha, Unani, Yoga and folk medicinal knowledge which has been preserved and handed down from generation to generation (Ansari, 2019). But as the commercialization of biological resources and turmeric, neem, and basmati cases of biopiracy were increasing, it was becoming necessary to have a robust legal framework which would govern access to biological resources and benefit sharing and would ensure that the knowledge holders receive fair and equitable benefits (José & Manchikanti, 2021). In order to comply with the Convention on Biological Diversity (CBD) and the Nagoya Protocol, India passed several laws and institutions concerning biodiversity conservation, Access and Benefit Sharing (ABS) and protection of traditional knowledge. The Indian legal system primarily consists of the Constitution, the Biological Diversity Act, 2002, Biological Diversity Rules, 2004, Protection of Plant Varieties and Farmers' Rights Act, 2001, Patent Act, 1970 and the Traditional Knowledge Digital Library (TKDL).

2.1 Constitutional Framework

The Constitution of India gives a significant platform for the conservation of biodiversity and protection of environment. Article 48 A of the Directive Principles of State Policy mandates the State to protect and improve the environment and secure a sustainable supply of natural resources like forests, wildlife etc. In the same way, Article 51A(g) has given it as a fundamental duty to all citizens to protect and improve the natural environment, including the forests, lakes, rivers, and wildlife. The provisions are in accord with the Sustainable Use of Biological Resources and the Protection of Traditional Knowledge related to Biodiversity. In India, environmental protection has also been declared as a part of the right to life in Article 21 of the Constitution of India.

2.2 Biological Diversity Act, 2002

The major legislation in India that regulates the conservation of biodiversity and ABS is the Biological Diversity Act, 2002. The Act was passed to help put into practice the aims of the Convention on Biological Diversity (CBD), which are:

Conservation of biological diversity

Sustainable use of biological resources

Fair and equitable sharing of benefits arising from utilization of biological resources

The Act governs the utilization of biological resources and traditional knowledge associated with it and safeguards against any unauthorized exploitation or biopiracy (Trivedi, 2024).

The Biological Diversity Act establishes a three-tier institutional mechanism:

National Biodiversity Authority (NBA)

State Biodiversity Boards (SBBs)

Biodiversity Management Committees (BMCs)

Access by foreign individuals, corporations and non-resident Indians to biological resources or associated TK requires prior approval from the National Biodiversity Authority for research, commercial use or for any applications leading to intellectual property rights. The Act also includes provisions for benefit sharing such as royalties, joint ownership of intellectual property rights, technology transfer, joint research and socio-economic development of local communities (Bajpai & Sikarwar, 2024).

2.3 Biological Diversity Rules, 2004 and ABS Regulations

The Biological Diversity Rules, 2004 have been framed to implement Biological Diversity Act, 2002. The Rules outline the procedure for gaining access, ABS agreements, transfer of research results, and benefit sharing agreements. ABS Regulations are designed to reinforce the implementation of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) in Indian law. They grant the National Biodiversity Authority the autonomy to calculate the benefit-sharing obligations, taking into account the extent of traditional knowledge used, the socio-economic benefits of the commercial utilization and to local communities. The Rules also promote the preparation of People's Biodiversity Registers (PBRs) that record the biological resources and traditional knowledge in a local area. The Protection of Plant Varieties and Farmers' Rights Act, 2001 (2.4) is a law that aims to safeguard plant varieties and farmers' rights.

2.4 Protection of Plant Varieties and Farmers' Rights Act, 2001

India adopted a sui generis system for plant variety protection through the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001 in compliance with Article 27.3(b) of the TRIPS Agreement.

Ensure that plant breeders' rights are respected

Respect farmers' efforts for plant biodiversity conservation

Encourage the development of new varieties of plants

Make sure that farmers' rights are respected and benefit is shared.

One of the main strengths of the PPVFR Act is that it acknowledges the farmers as holders of plant genetic resources as cultivators, conservers and breeders. The Act enables benefit sharing arrangements with the local communities that provide traditional varieties, which can include compensation from breeders who make use of the local resource (Humphries et al., 2022).

2.5 Patent Act, 1970 and Traditional Knowledge Protection

India made a modification to the Patent Act 1970 to safeguard against the biopiracy and wrongful patenting of traditional knowledge. Section 3(p) of the Patent Act excludes from patentability: "an invention that is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components." The Patent Act further mandates disclosure of origin and source of biological material(s) incorporated in an invention. Opposition and/or revocation of patents may be imposed for failure to disclose such information. The amendments have been brought in primarily because of international conflicts related to patents on turmeric, neem, and basmati rice (José & Manchikanti, 2021).

Table 2: Important Provisions under Patent Act, 1970 (Source: Patent Act, 1970)

Provision	Objective
Section 3(p)	Prevent patenting of traditional knowledge
Disclosure Requirement	Identification of biological source
Patent Opposition	Challenge wrongful patents
Revocation Provision	Cancel illegally obtained patents

2.6 Draft Protection of Traditional Knowledge Bill, 2022

The Draft Protection of Traditional Knowledge Bill, 2022 proposes to establish a dedicated legal mechanism for protecting, preserving, promoting and sustainable development of TK in India.

The proposed Bill aims to:

Identify TK holders' rights

Prohibit unauthorised commercial use

Encourage a fair distribution of benefits

Facilitate access to traditional knowledge

Assess and reinforce institutional arrangements for the governance of TK

The Bill also aims to establish regulating and protecting authorities for TK, and provide for a stronger role for indigenous communities in decision-making.

3. ABS Models and Biopiracy Cases

Access and Benefit Sharing (ABS) models are tools designed to manage access to biological resources and traditional knowledge, and to provide equitable and fair sharing of benefits generated from the use of these resources. The goal of ABS is to reconcile the conflicting values of biodiversity conservation, scientific research, commercial use, and the protection of indigenous and local communities that value traditional knowledge and biological resources (Bajpai & Sikarwar, 2024). The introduction of the Convention on Biological Diversity (CBD), 1992 and the Nagoya Protocol, 2010, put a spotlight on the importance of ABS, by introducing access to genetic resources as a matter of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) at an international level (Reichman, 2019). Concurrently, there was a rise in the commercialization of biological resources and a number of cases of biopiracy, where biological resources were patented or used commercially without permission or benefit sharing with indigenous peoples. These cases revealed gaps in international IP systems and the need for proper ABS frameworks and protection of TK systems (Bond & Scott, 2020).

3.1 Nagoya Protocol ABS Model

The Nagoya Protocol model is the most commonly approved international ABS model. It is based on three important principles:

Prior Informed Consent (PIC)

Mutually Agreed Terms (MAT)

Fair and Equitable Benefit Sharing

Under this model, users of genetic resources must obtain prior approval before accessing biological resources and negotiate benefit-sharing arrangements with provider countries and indigenous communities (Bajpai & Dixit, 2025).

The Nagoya Protocol emphasizes transparency, legal certainty, biodiversity conservation, and participation of indigenous communities. India follows this ABS framework through the Biological Diversity Act, 2002 and ABS Regulations.

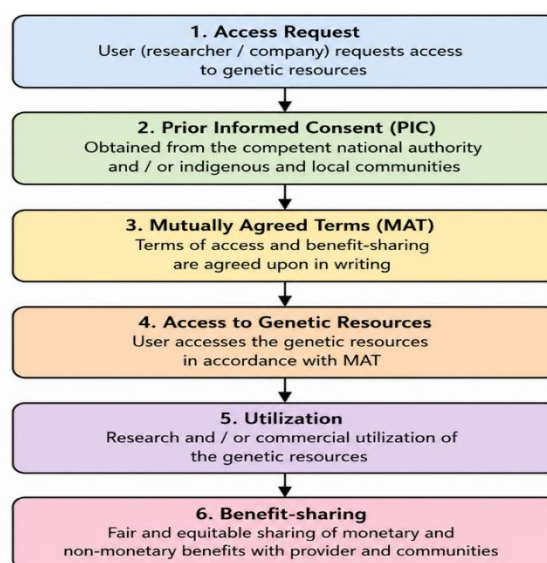


Figure 1: Nagoya Protocol ABS Model -Nagoya Protocol, 2010; Bajpai & Dixit (2025).

3.2 One Contract Model

One Contract Model means that all stakeholders are involved in a single contract that covers access, use, IPRs and benefit sharing. Access and benefit sharing arrangements are negotiated by the government, researchers, corporations and indigenous communities collectively. Transparency and collective participation are encouraged, but negotiations with several stakeholders may be lengthy and challenging to coordinate, increasing the complexity of this model (Humphries, 2025).

Advantages

Greater transparency
Inclusive participation
Reduced legal disputes

Limitations

Complex negotiations
Administrative difficulties
Delays in agreement process

3.3 Wheel-of-Contracts Model

The Wheel-of-Contracts Model is a set of bilateral contracts linked together through a coordinating institution or a lead organization. There is a “hub” institution and separate agreements are made with local communities, research institutions, corporations, and government authorities. This is a flexible model and enables separate negotiations with various stakeholders (Humphries et al. 2022).

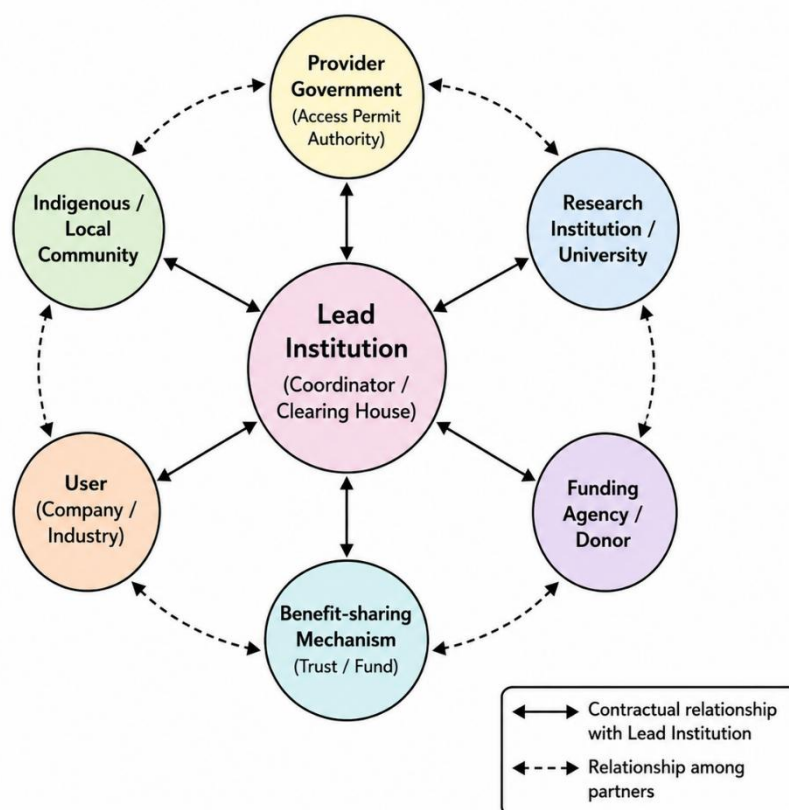


Figure 2: Wheel-of-Contracts Model

3.4 Dual Contract Model

The Dual Contract Model separates ABS arrangements into two agreements:

Resource Access and Benefit-Sharing Agreement
Commercial Research and Development Agreement

The first agreement governs access to biological resources and traditional knowledge, the second the commercialization, IPR and licensing agreements. This model allows culturally sensitive issues relating to traditional knowledge to be separated from commercial research activities (Bond & Scott, 2020).

Table 3: Dual Contract ABS Model

Agreement Type	Main Purpose
Resource Access Agreement	Access to biological resources and TK
Commercial Agreement	Commercialization and IPR management

3.5 TBGRI–Kani (Jeevani) Model

The TBGRI–Kani model is a very vital ABS case study in India. At the Tropical Botanic Garden and Research Institute (TBGRI), an anti-fatigue herbal medicine “Jeevani” was formulated based on traditional knowledge shared by the Kani tribal community on the medicinal plant called Arogyapacha. In this instance, TBGRI agreed to share part of the licence fee and royalties with the Kani community, and it is one of the earliest cases of benefit sharing in India (José and Manchikanti, 2021). The Jeevani model stands out as a significant case of community involvement and sharing of benefits. But obstacles to benefit distribution and long-term community involvement were noted, too.

Table 4: TBGRI–Kani Model

Aspect	Details
Biological Resource	Arogyapacha plant
Traditional Knowledge Holder	Kani Tribe
Product Developed	Jeevani
Benefit Sharing	Royalty and license fee sharing

3.6 Pinak Tablet Case

The case of the Pinak Tablet is a significant instance of traditional knowledge in India used in the manufacturing of medicine. The medicinal plants which have long been used to treat snake bites were used to develop the product. The National Biodiversity Authority has sanctioned benefit-sharing agreements with regards to commercialization of the product. The case illustrates the application of ABS principles in the context of Biological Diversity Act, 2002 and India's attempt in regulating commercial utilization of Traditional Knowledge.

3.7 Wild Rice Gene Case

In the case of Wild Rice Gene, the disease resistant gene was transferred from wild rice in Mali. Later on, the gene was used at international research institutes and patented after being developed scientifically. While efforts have been made to implement benefit-sharing mechanisms using a Genetic Resource Recognition Fund, case studies have shown that there are several challenges in claiming ownership, equitable compensation and the protection of countries of origin interests (Humphries et al., 2022).

3.8 Prostratin–Mamala Tree Model

The Prostratin–Mamala Tree model was based on the indigenous knowledge of Samoa's medicinal knowledge about the Mamala tree traditionally used for the treatment of viral diseases. Researchers worked with local communities, and negotiated agreements regarding future commercialization and benefit sharing. It was a case of incorporating indigenous knowledge into the process of medicinal product development at the same time trying to ensure that community participation and benefit sharing (Bajpai & Sikarwar, 2024) are achieved.

3.9 Merck–INBio Agreement

The Merck–INBio agreement is one of the first international ABS models with the National Biodiversity Institute (INBio) in Costa Rica and the pharmaceutical firm, Merck.

Under the agreement:

INBio provided biological samples for pharmaceutical research

Merck funded biodiversity research and conservation activities

Benefits included research funding, infrastructure support, and technology transfer

While the agreement facilitated biodiversity conservation, some critics noted that indigenous peoples were not directly engaged in negotiations and were not fully benefiting from them (Bond & Scott, 2020).

Table 5: Comparative Analysis of ABS Models

Case	Country	Benefit Sharing Type	Major Issues
TBGRI–Kani Model	India	Royalty sharing	Distribution challenges
Merck–INBio	Costa Rica	Research funding	Limited community participation
Prostratin Model	Samoa	Profit-sharing agreement	Commercialization concerns
Wild Rice Gene Case	Mali	Recognition fund	Ownership disputes

3.10 Role of TKDL in Preventing Biopiracy

India has created the Traditional Knowledge Digital Library (TKDL) to prevent wrongful patenting of traditional medicinal knowledge. The traditional formulations mentioned in the TKDL documents can be used by the patent examiner for taking the prior art information (Ansari, 2019). The TKDL has contributed greatly in stopping biopiracy by helping patent offices across the world to refuse patents on traditional medical knowledge. The incorporation of traditional knowledge into the global patent examination processes has been revolutionised by TKDL, according to Fredriksson (2021). Suggested Figure 3: Role of TKDL in Preventing Biopiracy

3.11 Significance of ABS Models and Biopiracy Regulation

ABS models and anti-biopiracy mechanisms are essential for ensuring:

Biodiversity conservation

Protection of indigenous knowledge

Equitable economic benefits

Sustainable development

Ethical scientific research

Prevention of exploitation of local communities

Good ABS governance improves the rights of the people and helps achieve a balance between innovation and conservation of biological resources. Yet, some issues that impact the implementation of global ABS are still present including those related to digital genetic resources, weak enforcement and unequal bargaining power.

4. Judicial Approach and Challenges in ABS Implementation

Judicial interpretation of Access and Benefit Sharing (ABS), biodiversity conservation and the protection of traditional knowledge (TK) has been instrumental in strengthening the legal framework concerning biological resources and indigenous rights, in India. Indian courts have increasingly acknowledged the importance of the conservation of biodiversity, sharing benefits in an equitable manner, and protecting against biopiracy. Judicial rulings have also highlighted the importance of weighing IP rights against the rights of TK/Indigenous/Local Communities that safeguard TK and biological resources (Trivedi, 2024). Though India has a detailed legislation like the Biological Diversity Act, 2002 and Protection of Plant Varieties and Farmers' Rights Act, 2001, there have been numerous practical and legal hurdles in the effective implementation of ABS mechanisms in India. There are still many concerns such as weak enforcement systems, and limited participation of indigenous communities, commercial exploitation of biological resources, biodiversity loss and conflicts between IP rights and TK (Bajpai & Sikarwar, 2024).

4.1 Divya Pharmacy v. Union of India

The Divya Pharmacy case is one of the most significant cases concerning the implementation of ABS in India. The issue was whether the Indian companies using biological resources and traditional knowledge for commercial

applications had to abide by the requirement of benefit sharing under the Biological Diversity Act, 2002. The Uttarakhand High Court said in its order that the Indian companies must share the benefits on the utilization of biological resources and associated traditional knowledge for commercial purposes with the indigenous and local communities. This Court noted that, apart from conservation of biodiversity, the Biological Diversity Act was meant to ensure the equitable distribution of benefits to the communities that maintain such knowledge. (Trivedi, 2024)

Significance of the Case

Strengthened ABS obligations in India

Recognized rights of indigenous communities

Promoted equitable benefit sharing

Expanded interpretation of the Biological Diversity Act

4.2 Research Foundation Case

The Research Foundation for Science, Technology and Ecology case was focussed on the problems of biopiracy and patenting of Indian biological resources in foreign countries. The lawsuit relates to patent rights for Indian wheat varieties and questions about the protection of biodiversity and traditional agricultural knowledge. The case brought to spotlight the vulnerability of Indian biological resources in the IP systems of the international community and the need for strengthening government action against biopiracy (José & Manchikanti, 2021). Judiciary recognized the need to safeguard biodiversity and promoted the creation of legal and institutional arrangements for the protection of traditional knowledge and the prevention of unearned patenting of biological resources.

4.3 Bt. Brinjal Litigation

The Bt. Brinjal controversy was an issue of concern related to issues of biodiversity protection, bio-safety and regulatory lapses in India. Public interest petitions complained about the unauthorized use of local varieties of brinjal and failure to comply with the provisions of the biodiversity laws and ABS obligations.

The litigation highlighted several important issues:

Failure to obtain proper approvals under biodiversity laws

Lack of participation of local communities

Risks to biodiversity and environmental sustainability

Regulatory gaps in monitoring genetically modified crops

The case highlighted how environmental litigations are playing an increasing role in safeguarding biodiversity and indigenous agricultural knowledge systems (Iskander Bond, Scott, 2020).

4.4 Judicial Protection of Indigenous Rights

Indian courts have increasingly affirmed the value of conserving indigenous and local communities of biological resources and traditional knowledge. Decisions by the judiciary on environmental protection, tribal rights, and sustainable development have highlighted the need to engage local communities in biodiversity governance.

The judiciary has supported principles such as:

Sustainable development

Environmental justice

Community participation

Protection against exploitation of traditional knowledge

Equitable sharing of benefits arising from biological resources

These principles strengthen implementation of ABS mechanisms and promote protection of indigenous rights within biodiversity governance systems (Barpujari & Sarma, 2017).

4.5 Lack of Participation of Indigenous Communities

Indigenous and local communities' lack of involvement in decision-making processes is one of the key problems for implementing ABS. While there are provisions in the Biological Diversity Act for Biodiversity Management Committees (BMCs), the participation of communities in ABS negotiations is sometimes limited in practice. In

many instances, the corporations and research institutions directly engage with the government authorities, with indigenous communities sidelined from discussions around benefit sharing and commercialization of TK (Humphries et al., 2022). Lack of effective engagement decreases transparency and diminishes protection of community rights in ABS systems.

4.6 Issues Relating to PIC and MAT

Two key concepts of the Nagoya Protocol are Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). But, there are several challenges in India to implement PIC and MAT.

There is limited knowledge of the indigenous communities.

An imbalance in negotiating power between business and local communities Lack of standardized procedures:

Lack of standardized procedures:

The failure to have clear discussions with the parties

Insufficient clarity in discussion with the parties.

The levels of compliance are low.

Compliance is poorly monitored.

Such situations lead to inadequate protection for traditional knowledge holders' rights and interests in benefit-sharing agreements (Lee & Chang, 2024).

As a result, benefit-sharing agreements often fail to adequately protect the rights and interests of traditional knowledge holders (Lee & Chang, 2024).

4.7 Conflict between Intellectual Property Rights and Traditional Knowledge

The protection of traditional knowledge and traditional cultural expressions within the context of IPR. Conflict between IPR and Traditional Knowledge and Traditional Cultural Expressions. The protection of traditional knowledge (TK) and the protection of intellectual property rights (IPR) is one of the most critical issues that ABS managers are facing. Traditional knowledge is community-based and passed on from generation to generation, while conventional patent systems rely on notions of individual ownership and novelty (Trivedi, 2024). Multiple cases of biopiracy showed how corporations tried to patent knowledge already in the hands of indigenous people, as applied to the field of medicine and agriculture. There was a lack of ability on the part of the typical IPR systems to properly acknowledge collective community rights in such incidents.

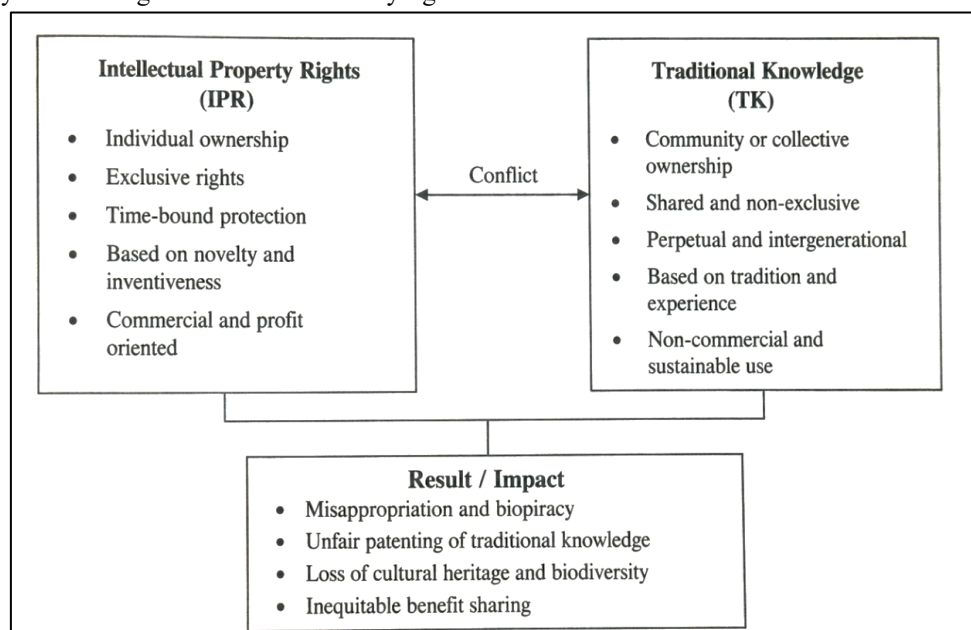


Figure 3: Conflict between IPR and Traditional Knowledge

The conflict has left legal uncertainty regarding the rights of ownership and access to traditional knowledge and their associated benefits.

5.8 Digital Sequence Information (DSI) and Emerging Challenges

New challenges with Digital Sequence Information (DSI) have arisen recently with the developments of biotechnology and genomics. Digital storage and use of genetic information, without the need to access biological materials, is now possible, which could circumvent traditional ABS obligations (Akpoviri et al., 2023).

Digital utilization of genetic resources creates several concerns:

Difficulty in tracing origin of genetic resources

Regulatory uncertainty regarding ABS obligations

Possibility of digital biopiracy

Weak international governance mechanisms

Bond and Scott (2020) describe this emerging issue as “digital biopiracy,” where digitized biological information may be commercially exploited without benefit sharing with provider countries and indigenous communities.

5.9 Need for Strengthening ABS Governance

Improvement of ABS implementation is needed to safeguard biodiversity, to ensure equitable benefit sharing, and to prevent traditional knowledge from being exploited and to support sustainable development. Judicial recognition of the rights of communities and the protection of biodiversity has been a huge contribution of the judicial approach in India. However, ongoing legal changes and institutional development are still required to tackle new challenges to ABS governance in a digital and globalised world.

6. Findings, Suggestions and Conclusion

6.1 Findings

The study shows that Access and Benefit Sharing (ABS) has become a significant international and national legal instrument for access to biological resources and equitable and fair sharing of benefits from their use. The Convention on Biological Diversity (CBD) and the Nagoya Protocol set important principles like Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and equitable benefit sharing in the case of protection of biodiversity and traditional knowledge (TK) (Reichman, 2019). The research also reveals that India has enacted a relatively extensive legal framework for protection of biodiversity and traditional knowledge with its Biological Diversity Act, 2002, Biological Diversity Rules, 2004, Protection of Plant Varieties and Farmers' Rights Act, 2001, Patent Act, 1970 and the Traditional Knowledge Digital Library (TKDL). These laws have been enacted to find a balance between biodiversity conservation, IPR, scientific innovations and community rights (Ansari, 2019). The study also reveals that in cases of turmeric, neem, ‘basmati’ and ‘Nap Hal’ wheat, the classical intellectual property regimes were found to be lacking in terms of protection for TK. They raised the awareness of the need for defensive protection measures such as TKDL and better implementation of ABS (José & Manchikanti, 2021). While there are legal frameworks in place, there are still a number of practical and legal problems in ABS governance in India. Indigenous and local communities may not be well represented in ABS negotiations and benefit-sharing mechanisms. The ability of ABS systems to be effective is undermined by weak enforcement mechanisms, lack of awareness, unequal bargaining power, and delays in implementation (Humphries et al., 2022). The research also notes that new legal questions regarding ownership, access and obligations for benefits are raised by the new technologies that are seen as emerging Digital Sequence Information (DSI). While the current laws of ABS primarily focus on physical access to biological resources, they are inadequate in tackling the digital use of genetic information (Akpoviri et al., 2023).

Table 6: Major Findings of the Study

Area	Findings
International Framework	CBD and Nagoya Protocol strengthened ABS principles
Indian Legal Framework	Comprehensive but implementation gaps exist
Traditional Knowledge Protection	TKDL plays an important role against biopiracy
Indigenous Participation	Limited participation in ABS negotiations
Enforcement Mechanisms	Weak monitoring and compliance systems
Emerging Challenges	DSI and digital biopiracy create legal uncertainty

Source: Prepared from analyzed literature and legal framework.

6.2 Suggestions and Recommendations

Based on the results, there are some legal and policy changes required for effective governance and protection of the TK in India.

(1) Enabling Indigenous Communities to be more Resilient to Climate Change

Indigenous and local people need to be at the table in all phases of ABS negotiations and decision making processes. They should not be just token participants. Biodiversity Management Committees (BMCs), State Biodiversity Boards (SBBs) and ABS regulatory bodies (Barpujari & Sarma, 2017) should be well represented with community representatives.

(2) Prior Informed Consent (PIC) is a requirement.

Pursuant to the principle of Prior Informed Consent, access to biological resources and traditional knowledge should be given only after the consent is obtained. To ensure the informed consent of indigenous communities, they should be provided with all the necessary information about commercial use, research activities, and benefit-sharing arrangements (Lee & Chang, 2024).

(3) Strong Anti-Biopiracy Mechanisms

India should set up a special body to monitor the presence of incorrect patents in international forums for biological resources and TK. There should also be strong international cooperation amongst the patent offices and the biodiversity authorities (Ansari, 2019).

(4) Improving TKDL and Digital Protection Systems

It is recommended that the Traditional Knowledge Digital Library (TKDL) be updated and expanded more to include more traditional medicinal formulations, traditional biodiversity related knowledge etc. Legal instruments should also be put in place to control Digital Sequence Information (DSI) and to stop digital biopiracy (Fredriksson, 2021).

(5) Special ABS Dispute Resolution Mechanism has been established.

Arbitration and/or a benefit sharing and community rights tribunal ought to be set up to resolve issues regarding benefit sharing, community rights and IP issues related to ABS. Efficient and speedy dispute resolution would enhance ABS implementation and enforcement.

(6) Better Coordination among Regulatory Authorities

There is need of efficient coordination between the National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs), Biodiversity Management Committees (BMCs), patent authorities and TKDL administration for proper governance for efficient ABS and protection of biodiversity.

(7) A package of regulations has been created to manage the flow of Digital Sequence Information (DSI).

India needs to establish a proper regulatory framework for Digital Sequence Information and digital genetic resources. The existing ABS laws need to be updated to guarantee that uses of genetic resources that are made in a digital format do not circumvent the obligations arising from ABS (Kharb, 2021).

(8) Cooperation at the International level for traditional knowledge protection.

Worldwide cooperation for protection of TK and prevention of biopiracy should be strengthened by international bodies like WIPO, WTO and CBD bodies. Biological material should be disclosed as source and origin of materials should be made mandatory within the international patent system.

6.3 Conclusion

Access and Benefit Sharing (ABS) is an important legal and ethical approach to access to biological resources, and to equitable sharing of benefits from their use. ABS mechanisms acknowledge the role of indigenous and local communities in protecting the biological diversity and traditional knowledge for many generations.

The Convention on Biological Diversity (CBD) and the Nagoya Protocol, among other international agreements, played a significant role in the creation of legal frameworks for biodiversity conservation, community rights, and equitable benefit-sharing (Bajpai & Dixit, 2025).

India has a relatively well-established legal regime for the protection of biodiversity, including the Biological Diversity Act, 2002, the ABS Regulations, the Traditional Knowledge Digital Library and the Patent Act, which include a definition of traditional knowledge. India has an intermediate legal regime for the protection of

biodiversity, including the Biological Diversity Act, 2002, the ABS Regulations, the Traditional Knowledge Digital Library, and the Patent Act, which contains a definition of traditional knowledge. India has put in place such measures that have bolstered the protection of its traditional medicinal knowledge from the perspective of biopiracy and wrongful patenting. The TKDL, especially, has proved a useful tool to safeguard TK under IPS (Yadav & V., 2024). But there are some drawbacks which are still hampering the efficient implementation of the ABS system in India.

There are concerns regarding weak enforcement mechanisms, lack of participation of the indigenous communities, the commercialisation of biological resources, loss of biodiversity, and conflict between IP rights and traditional knowledge. The rise of new technologies connected to Digital Sequence Information (DSI) adds to the complexity of ABS governance and poses risks of digital biopiracy (Akpoviri et al., 2023).

Thus, ongoing legal changes, improved institutional arrangements, active involvement of the communities and international collaboration are essential to achieve the balance between biodiversity conservation and scientific innovation with the protection of TK and IR. ABS governance will be strengthened and will not only deter biopiracy but also ensure sustainable development, environmental justice and equitable use of biological resources in the future.

Conflict of interest

None

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