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## Protecting India's Traditional Medical Knowledge: Navigating Intellectual Property Rights and Equitable Benefit Sharing

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### Abstract

Traditional medical knowledge (TMK), encompassing the medicinal use of plants and other natural substances, is a vital health resource for indigenous communities worldwide. As interest in traditional medicines has grown among researchers and pharmaceutical companies seeking new drug leads, questions have arisen regarding the ownership of this knowledge and how communities can benefit from its commercial development while preserving their cultural heritage. The debate centers on applying intellectual property rights (IPR) frameworks, originally designed to protect individual innovations, to collectively-held traditional knowledge. Efforts to resolve these issues have included sui generis IP systems, access and benefit sharing agreements, defensive knowledge repositories, and disclosure of origin requirements. However, obstacles remain in creating approaches that are practical, enforceable, and balance the interests and worldviews of knowledge-holding communities, national governments, and the private sector. India, with its rich history of traditional medical systems like Ayurveda, Siddha and Unani, has been at the forefront of these debates. Through legislative measures like the Biological Diversity Act and Patents Act as well as pioneering initiatives like the Traditional Knowledge Digital Library, India has sought to prevent misappropriation of its TMK while exploring avenues for its protection and equitable commercialization. However, challenges persist in ensuring adequate legal protection, stakeholder participation, and benefit sharing.

Addressing these complex issues will require the creative adaptation of IPR tools through policies that respect rights and foster equitable partnerships. Political will and the active involvement of indigenous peoples and local communities will be key to developing solutions that support their wellbeing alongside biodiversity conservation and scientific advancement. Case studies from India offer valuable lessons to inform the ongoing search for appropriate mechanisms to protect TMK and ensure equitable benefit sharing

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## 1. Introduction

Traditional medicine, encompassing the knowledge and practices indigenous cultures have developed over centuries to maintain health and treat disease, plays a vital role in meeting global healthcare needs. The World Health Organization estimates that 80% of people in developing countries rely on traditional remedies, especially medicines derived from plants, as their primary source of healthcare. Even in industrialized nations, use of traditional and alternative medicine is gaining popularity, with the global market for herbal products reaching US\$60 billion annually.

As demand for traditional plant medicines has grown, so too has interest from researchers and pharmaceutical companies in accessing this knowledge to develop new drugs. Indian systems of medicine like Ayurveda, Siddha and Unani, with their extensive pharmacopeias and centuries-old texts documenting the use of thousands of plants, have been a particular target of bioprospecting efforts. Of the 119 drugs developed from higher plants on the world market today, an estimated 74% were discovered through research on plants used in traditional medicine.

This reliance on traditional knowledge for drug discovery has raised concerns about how local and indigenous communities can benefit from the commercialization of their cultural heritage while preserving it for future generations. At the heart of the matter are questions about whether intellectual property rights (IPR) frameworks, originally designed to protect innovations by individuals and companies, can and should be extended to collectively-held traditional knowledge that has evolved over generations.

India, one of the world's top mega-biodiverse countries, has 15 agro-climatic zones with distinct indigenous communities who have developed unique traditional knowledge of using biological resources, including for medicinal purposes. The value of India's TMK for health and economic development has thrust the country into the center of global discussions on IPR and benefit sharing.

Through legislative measures like the Biological Diversity Act and Patent Act amendments as well as initiatives like the Traditional Knowledge Digital Library, India has sought to prevent misappropriation of its TMK while exploring IPR protection avenues. However, developing an appropriate sui generis legal framework that respects the nature of TMK and ensures equitable benefit sharing remains a work in progress.

This paper explores the IPR challenges raised by TMK in the Indian context, reviews the solutions proposed and attempted so far, and discusses considerations for policies that can effectively foster equitable benefit sharing and protection of TMK as a living heritage. Section 2 provides background on

the Indian medical heritage and the role of IPR in the TMK debate. Section 3 analyzes the key issues around applying patents and other IPR tools to protect TMK. Section 4 discusses alternative legal and policy frameworks being explored. Finally, Section 5 offers conclusions and recommendations in the Indian context, drawing on case studies.

## **2. Background**

### **2.1 India's Traditional Medical Heritage**

India is home to several codified traditional medical systems—Ayurveda, Siddha, Unani, Yoga and Naturopathy—as well as diverse folk medicine traditions. Ayurveda, the "science of life," is a 5000-year-old system with an extensive literature including the Charaka Samhita and Sushruta Samhita. The Siddha system, prevalent in South India and Sri Lanka, has roots in the ancient Tamil civilization. The Unani Tibb system, introduced by Arabic and Persian settlers, draws heavily on the principles proposed by Hippocrates and Galen. These systems employ a vast pharmacopeia of plants, animals and minerals used as single drugs or poly-herbal formulations.

In addition to the codified systems, local health traditions and folk practices handed down orally over generations play a significant role in meeting people's primary care needs, especially in rural areas. India has over 54 million indigenous people belonging to 550 tribes spread across 5000 forest villages. Tribal communities like the Kani, Irula, and Soliga have developed unique TMK shaped by their ethnic origins and the diverse ecologies they inhabit and depend on.

Traditional medicine remains the primary source of healthcare for 70% of India's rural population. Over 7800 licensed drug manufacturing units produce traditional medicines to meet this demand, generating annual revenues of about USD \$1 billion. Export of medicinal plants and herbal products also forms a major source of income, with exports valued at over USD \$98 million in 2012-13.

### **2.2 Intellectual Property and TMK in India**

The realization of the economic value of TMK and its importance for drug discovery has fueled efforts to secure IPRs over this knowledge in recent decades. However, the collective, place-based and incrementally evolving nature of TMK sits uneasily with conventional IPR systems designed to reward individually-held, novel innovations.

India's TMK has been a particular target for biopiracy by foreign entities. In a well-known case, the US Patent and Trademark Office in 1995 granted the University of Mississippi Medical Center a patent on

the wound healing properties of turmeric despite the lack of novelty. The Indian Council of Scientific and Industrial Research (CSIR) challenged the patent, submitting 32 references from ancient Sanskrit texts and an article from 1953 in the Journal of the Indian Medical Association documenting prior art. The patent was revoked in 1997, marking the first successful reversal of a biopiracy patent.

Other high-profile cases have involved attempted patents on the anti-fungal properties of neem, an antipyretic made from *Phyllanthus amarus*, and a treatment for vitiligo derived from *Psoralea corylifolia*. Although international conventions like the Convention on Biological Diversity (CBD) and the Nagoya Protocol recognize national sovereignty over genetic resources and associated TMK, countries like the US do not mandate disclosure of origin in patent applications. This has left India's TMK vulnerable to misappropriation.

To address these gaps, India has adopted a multi-pronged legal approach involving amendments to the Patents Act, a sui generis law to protect biodiversity and TMK in the Biological Diversity Act (BDA), and the creation of a defensive prior art database, the Traditional Knowledge Digital Library. Section 3(p) added to the Patents Act excludes from patentability "an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components." The BDA mandates prior approval from the National Biodiversity Authority (NBA) to obtain IPRs on any invention based on biological resources occurring in or obtained from India.

While these measures help prevent third parties from directly claiming patents over existing TMK, they do not address the positive protection of TMK or the IP-related challenges facing Indian medical systems in their efforts to translate TMK into new products and innovations. Limitations in the existing IPR toolkit to accommodate TMK have led to a search for alternative sui generis models.

### **3. Applying IPRs to Protect TMK: Key Challenges**

#### **3.1 Novelty and Prior Art**

The criteria of novelty poses a major barrier to protecting TMK with patents. Traditional medicines based on knowledge already available in ancient texts or handed down through generations are considered pre-existing "prior art" in patent law and hence not novel. Yet when a researcher or company makes minor modifications to this TMK and files a patent, sometimes they succeed in doing so, amounting to a form of biopiracy that provides no benefits to TMK holding communities.

Even when patent laws prohibit the patenting of TMK, as in the case of India's Patents Act Section 3(p), proving the prior art status of TMK can present evidentiary challenges. Most TMK is contained in regional

languages and ancient scripts rather than in searchable multilingual databases. It is also often described in terms not easily recognized by patent examiners trained in Western scientific nomenclature.

To overcome this barrier, India pioneered the creation of the Traditional Knowledge Digital Library (TKDL), an electronic database that contains information on 2.97 lakh medicinal formulations used in Ayurveda, Unani, and Siddha. By translating TMK from ancient texts into five languages (English, German, Japanese, French, Spanish) and formatting it as per international patent specifications, TKDL serves as a bridge between TMK and the international patent system. It allows patent examiners to search and locate relevant prior art, a preventative mechanism to avoid the granting of inappropriate patents.

TKDL's impact has been noteworthy - its use as prior art has led to the withdrawal or rejection of patent applications concerning TMK in several countries. As of 2022, 239 patent applications have been withdrawn, amended or set aside based on TKDL evidence submitted to international patent offices. However, public access to the full TKDL database remains restricted.

### **3.2 Inventiveness**

The patent criterion of non-obviousness or inventive step requires that an invention should not be obvious to a person skilled in the art. Again, this tends to exclude most TMK which constitutes either existing knowledge or minor modifications to known practices that would be considered obvious by a traditional practitioner.

However, there is growing recognition in India that TMK systems are not entirely static and have their own methodologies for innovation that differ from Western paradigms of inventiveness. Combinations of traditional ingredients validated by modern scientific evidence or novel extraction techniques and delivery systems for TMK can qualify as non-obvious innovations deserving of protection.

New uses for traditional medicines, such as a diabetes drug made from swerchirin found in *Enicostemma littorale* or anti-psoriatic effects of *Psoralea corylifolia*, are patentable if a new use with proper inventive steps and appropriate claims is made. Scholars argue that better extraction techniques, enhanced bioavailability, synergistic effects of polyherbal medicines and biotechnology-based novel applications should be recognized as innovations deserving of protection.

### **3.3 Community Ownership vs Private Rights**

TMK is generally held collectively by communities as a shared cultural heritage passed down through generations. This runs counter to patent law's focus on inventions by individual inventors or companies.

Even when TMK is held by specialized healers, communities still perceive it as collectively owned heritage that the practitioner holds in trust, not private property.

Vesting IPRs to a private entity for TMK is therefore problematic. It can disrupt customary laws and practices around TMK stewardship and sharing. Identifying a specific "owner" of TMK or an authoritative body to provide prior informed consent can be difficult in many communities with decentralized governance of TMK. Privatizing ownership of TMK can also facilitate its transfer to third parties outside the community's control.

A potential solution being explored is to expand the concept of geographical indications (GIs), designed to protect the reputations of goods associated with a particular locality, to protect TMK associated with a specific community/region. GIs are a collective right that recognizes the shared ownership of TK within communities of a region. The Indian GI Act allows for the registration of goods that derive their quality, reputation or characteristic from their geographical location including its people. Examples of registered GIs relevant to TMK in India include Kani tribal medicine, Coorg green cardamom, and Jhabua Kadaknath chicken meat.

### **3.4 Unstated Experiential Knowledge**

Much TMK relies on the experiential knowledge, careful observations, and accumulated evidence of generations of practitioners. It is often not amenable to the kind of written specifications in technical terms required for biomedical patents. TMK is embedded in cultural and ecological contexts. It is learned through traditional apprenticeships that acknowledge the dynamic, empirical nature of much TMK. Standard patent disclosure requirements thus can fail to capture the full depth and breadth of TMK.

Efforts to document TMK, while crucial for defensive protection, also carry the risk of de-coupling this knowledge from its roots and enabling commercial use by third parties without ensuring equitable benefits flow to local communities. India's TKDL attempts to avoid this by clarifying that "access to TKDL does not imply access to use this knowledge in any manner without the prior approval of the competent authorities."

## **4. Alternative Legal/Policy Frameworks**

### **4.1 Disclosure of Origin**

Incorporating a disclosure of origin (DOO) requirement in patent law can help address concerns about TMK and genetic resource appropriation. It would mandate patent applicants to disclose the source/origin

of biological resources and/or associated TMK used in an invention and provide evidence of prior informed consent and equitable benefit sharing per the CBD and Nagoya Protocol.

DOO proponents argue it would improve patent quality by enabling searches of relevant prior art, increase transparency, and facilitate the flow of benefits back to provider communities/countries. The majority of developing countries support amending the TRIPS Agreement to make DOO mandatory. However, many developed countries oppose a binding international DOO standard, viewing it as an unnecessary burden on the patent system.

While international negotiations remain gridlocked, several countries have incorporated DOO provisions in national laws. Indian patent law mandates a declaration of the source and geographical origin of biological material used in an invention per Section 10 of the Patents Act and Rule 12 of the Patent Rules 2003. The NBA approval for obtaining IPRs on inventions using Indian biological resources serves as a de facto DOO requirement.

## **4.2 Sui generis protection**

Given limitations in applying conventional IPRs to TMK, some have suggested developing alternative sui generis (unique) systems. Sui generis laws aim to directly address TMK's distinguishing features, such as collective ownership, community sovereignty, and the continuum between tangible and intangible property.

Key questions in designing sui generis laws include defining the protected subject matter, customizing criteria for protection, clarifying rights conferred and determining appropriate beneficiaries. Some models propose adapted forms of exclusive rights, while others suggest a "compensatory liability regime" where TMK users must pay equitable compensation but do not need prior authorization from TMK holders.

India's Biodiversity Act is considered a sui generis law for protecting TMK alongside biological resources. It combines a legal right of local communities to be consulted and provide prior consent for TMK access with a decentralized institutional mechanism of Biodiversity Management Committees (BMCs) representing local stakeholders. The Act mandates equitable benefit sharing for TMK use through material/technology transfer, joint IPRs, employment opportunities, monetary compensation or other means as determined by the NBA in consultation with benefit claimers.

In 2012, India's state of Andhra Pradesh introduced the Community Forest Resources Right Act, a sui generis law that offers a potential model. It establishes community forest rights and recognizes local governance of TMK associated with forest biodiversity. Gram sabhas (village councils) are empowered

to regulate TMK access and secure equitable benefits for their communities. Operationalizing these *sui generis* systems at local levels remains a challenge requiring major investments in community capacity-building.

### 4.3 Access and benefit-sharing contracts

Another tool being explored to protect TMK is the use of access and benefit-sharing (ABS) contracts directly between TMK providers and external users. Mutually-agreed terms in ABS contracts can cover issues like TMK ownership, scope/duration of use rights, benefit-sharing modalities, technology transfer, joint IPRs and dispute resolution. Community protocols that articulate local priorities and procedures for engaging with external actors can inform ABS contract terms.

India's Biodiversity Act and Rules provide a framework for ABS contracts and benefit-sharing negotiations overseen by the NBA in cases of TMK held by local communities. The NBA identifies relevant BMCs, consults with them and facilitates PIC processes. Specific benefit-sharing terms may be mutually negotiated between communities, the NBA and TMK users. Model ABS contract clauses are provided, but communities can suggest modifications.

Prominent Indian ABS cases have involved the Kani tribe's TMK about the anti-fatigue properties of Arogyapacha (*Trichopus zeylanicus*). The TBGRI research institute developed the drug "Jeevani" in consultation with Kani traditional healers. An ABS agreement was reached to share 50% of license fees and 2% of royalties with the tribe. Funds flow to the Kerala Kani Samudaya Kshema Trust which administers the money for community welfare projects. This agreement is considered an early model for equitable TMK commercialization.

More recently, the Bangalore-based company Avesthagen negotiated an ABS agreement with the Siddi tribe of Gujarat to share benefits from a diabetes drug derived from their TMK. The company agreed to pay royalties, provide community development funds, and share joint IPRs with the Siddis. However, some observers criticize the lack of full prior informed consent from the tribal governing bodies. These cases illustrate both the potential and pitfalls of ABS contracts for TMK.

To be truly fair and equitable, ABS arrangements require significant capacity-building of local communities to understand their rights and negotiate favorable terms. Without such empowerment, there are risks of unfair contracts and misappropriation of TMK. Government and civil society support in the form of legal aid, model contract clauses, and monitoring is crucial. Wider experience with implementing the Biodiversity Act's ABS provisions in TMK contexts is needed to refine best practices.



## 5. Recommendations & Conclusion

India's wealth of TMK is both a national treasure and a resource for potential commercialization to advance public health and sustainable development. Protecting this TMK from misappropriation while creating ethical pathways for innovation and equitable benefit-sharing is an urgent priority. Based on the preceding analysis of IPR challenges and emerging solutions in the Indian context, the following key recommendations emerge:

1. Strengthen defensive protection by expanding TKDL's coverage of TMK, linking it to state biodiversity registers, and allowing tiered access for research and patent examination.
2. Provide legal guidance and support to TMK holders in negotiating ABS contracts and securing equitable licensing/joint IPR terms with companies and researchers.
3. Pilot participatory approaches to registering TMK through community biodiversity registers and biocultural community protocols that document both existing uses and ongoing innovations per communities' customary laws.
4. Build capacities of BMCs and gram sabhas to catalogue TMK, provide PIC, and negotiate ABS and material transfer agreements.
5. Explore the potential of geographical indications to preventively protect TMK and economically benefit local communities and practitioners.
6. Develop sui generis legislation drawing on the Biodiversity Act framework, adapted to protect TMK and empower local communities as rights-holders and knowledge stewards.
7. Advocate for a globally harmonized mandatory disclosure of origin requirement and for equitable ABS principles in ongoing IPR and trade agreement negotiations.

In conclusion, India's efforts to navigate the tensions between IPRs, TMK protection and equitable benefit-sharing offer valuable lessons for many other countries grappling with similar issues. A one-size-fits-all approach is clearly inadequate given the diversity of indigenous medical traditions. A plurality of context-sensitive legal tools including PIC, ABS, sui generis rights, and customary law need to coexist and synergize.

At the heart of the matter are issues of self-determination, cultural integrity and economic justice for TMK-holding communities. Policies must be grounded in a rights-based approach empowering indigenous peoples and local communities as central actors - not just as beneficiaries but as decision-makers in the governance of their TMK. Bridging traditional and modern ways of knowing and sharing the benefits of TMK requires intercultural dialogue, political will, and new partnerships. India's

experiences, while still evolving, illuminate both the challenges and the creative possibilities for reimagining IPRs to respect and recognize traditional medical knowledge systems.

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