
INTEGRATING AYURVEDA INTO INDIA'S INTELLECTUAL PROPERTY RIGHTS FRAMEWORK: ADDRESSING EXPLOITATION AND PROTECTING TRADITIONAL KNOWLEDGE

Shreyasi Ghatak, Brainware University

Anurag Das, National Law University and Judicial Academy, Assam

ABSTRACT

Ayurveda is considered to be the oldest healing traditions in the world, the roots of Ayurveda can be traced back in India to the 2nd century BC and incorporates a rich archive of traditional knowledge (TK) which comprises of drug formulations, and comprehensive approaches to health. Despite of having global importance and value, Ayurveda suffers from insufficient protection under the current Intellectual Property (IP) rights ambit, its knowledge base is exploited by the companies and foreign bodies that markets Ayurvedic products for earning profit without having authorization and giving fair compensation to the concerned communities. It is difficult to bring Ayurveda under ambit of IP rights from the nature of TK, which is owned in collective manner, transmitted across generations, and mostly undocumented, which makes it challenging and unsuited with conventional IP systems that demands novelty and individual invention. This instance resulted in biopiracy, where ayurvedic components have been patented abroad, compelling India to meet such claims to retrieve ownership of its knowledge. Consequently, India came up with measures such as the Traditional Knowledge Digital Library (TKDL) and the Traditional Knowledge Resource Classification (TKRC), both of which document helped classifying Ayurvedic knowledge in structured manner, giving access to patent examiners globally to prevent the granting of wrongful patents. However, these mechanisms encountered a shortcoming in ensuring equitable benefit-sharing with indigenous practitioners and local communities. For addressing such drawbacks, Integration of emerging technologies like blockchain and watermarking systems could be an approach in order to secure authenticity and traceability of Ayurvedic formulations, accompanied by the development of worldwide benefitsharing frameworks and community-based certification models that would empower local custodians of knowledge. Enhancing protections in this manner would not only shield Ayurveda against misuse but also convert traditional

knowledge into a sustainable driver of cultural preservation, economic growth, and global health innovation.

Keywords: Ayurveda, Traditional Knowledge, Intellectual Property and Misappropriation.

Introduction

Ayurveda is deep-rooted in the Indian way of living and traces its beginning to over 3,000 years ago. It literally translates to "the science of life". It is etched with a rich history, confirmed in historical texts like Charka Samhita and Sushruta Samhita. These texts provide knowledge on health, including herbal treatments, eating patterns, and overall spiritual well-being¹. This exhaustive system categorized people into three distinct body-mind types, called '*doshas*' which includes - *Vata*, *Pitta* and *Kapha*. Each of these types require a customized treatment plan.² Through a wide range of therapies, including herb mixtures (rasayana, body cleanses (panchakarma), and lifestyle changes, Ayurveda tries to bring back balance and boost overall health giving a one-of-a-kind and long-standing approach to wellness³. The Ayurvedic medicine sector in India is experiencing tremendous growth. A study conducted in the year 2023 by a wellknown Ayurvedic tech startup named NirogStreet projects the market value to reach ₹1.2 trillion by 2028, reflecting a significant increase from ₹57,450 crores in 2022. This growth emerges from a multifaceted approach. Growing consumer interest in natural remedies, both at home and abroad, drives this increasing demand. The Government of India's creation of the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) has helped to develop medical education, research, and manufacturing⁴. This surge makes Ayurveda a significant member in the Indian healthcare sector. This article scrutinizes the intricate relationship between Ayurvedic medicines and Intellectual Property Law, understand the current hurdles to IP protection, consider potential challenges, and suggest a way forward.

¹ Lad, V., and D. Frawley. *The Yoga of Herbs* (Lotus Press, 1986).

² Lad, V., *Ayurveda: The Science of Self-Healing* (Penguin Books, 1984).

³ National Institutes of Health, 'Ayurvedic Medicine: In Depth' (National Center for Complementary and Integrative Health, 2022) <https://www.nccih.nih.gov/health/ayurvedic-medicine-in-depth> accessed 12 July 2024.

⁴ NirogStreet, 'Ayurveda products market in India to reach Rs 1.2 trillion by FY28: Report' (14 December 2023) <https://m.economictimes.com/industry/healthcare/biotech/healthcare/indias-ayurveda-product-market-to-reach-rs-12-lakh-crore-by-fy28-study/articleshow/109062773.cms> accessed 12 July 2024.

Intellectual Property Challenges in Protecting Ayurvedic Medicines

Ayurvedic medicines often don't have intellectual property (IP) protection because they come from old traditions as well as community practices handed down over time. The World Intellectual Property Organization (WIPO) says patent law doesn't cover discoveries and existing knowledge, like medicinal plants.⁵ Also traditional knowledge belongs to communities, not single inventors making it hard to patent ⁶. This creates problems in protecting Ayurvedic knowledge and encouraging research in modern IP systems. People worry that allopathic companies might take Ayurvedic knowledge without permission. Ayurveda's long history makes it tough to secure IP protection for its formulas. Without these safeguards, others can copy traditional remedies maybe even patenting similar allopathic drugs based on Ayurvedic ideas⁷. This brings up ethical issues about biopiracy and using traditional knowledge systems. We need more research to find other IP methods that can protect and boost innovation in Ayurveda⁸.

Legal Framework for the Protection of Ayurvedic Medicine

In India, the legal framework and the Intellectual Property Rights over traditional Knowledge is very weak. Any formula of ayurvedic medicine cannot be patented since its invention. Any traditional knowledge or duplication of known properties of traditionally known components have been made non-patentable under section 3(p) of the Patents Act, 1970.⁹ Though there is existing law governing the manufacturing of ayurvedic medicine. Rule 158-B of The Drugs and Cosmetics Rules, 1945 provides guidelines to issue a license to manufacture Ayurvedic, Siddha and Unani medicines in accordance with the evidence of safety and effectiveness.¹⁰ But, the IP rights over the invention of a new formula of ayurveda is very limited. Though under product patent, the provisions in the Patents Act do not allow patents to new inventions in the

⁵ World Intellectual Property Organization (WIPO), *Intellectual Property and Traditional Medical Knowledge* (Background Brief No. 6).

⁶ Chaudhary, A., 'Intellectual Property Rights and Patents in Perspective of Ayurveda' (2014) ResearchGate <https://www.researchgate.net/publication/> accessed 12 July 2024.

⁷ Shiva, V., *Biopiracy: The Plunder of Nature and Knowledge* (Zed Books, 2005).

⁸ Daniel, M., 'Protecting Traditional Knowledge and Medicinal Plants: A Review of Intellectual Property Options for India' (2006) 41(41) *Economic and Political Weekly* 4374-4382.

⁹ 'Use of Traditional Knowledge' (Press Information Bureau, 2013) <https://pib.gov.in/newsite/printrelease.aspx?relid=98021> accessed 12 July 2024.

¹⁰ Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy, *Rule 158-B Inserted in Evidence of Safety and Effectiveness* <https://sansad.in/getFile/loksabhaquestions/annex/11/AS324.pdf?source=pqals#:~:text=Rule%20158%20DB%20in,nse%20in,evidence%20of%20safety%20and%20effectiveness> accessed 12 July 2024.

field of Medicine. The amendments to the Patents Act in 2005 gave a broad scope of granting patents. New formulations and processes in Ayurveda could be patented, if they meet the criteria for patentability. New processes in these systems could be patented as could be seen from the process patent for Jeevani, an Ayurvedic drug developed by the Tropical Botanical Garden and Research Institute.¹¹ For preventing exploitation, IP protection is needed over Traditional Medical Knowledge (hereinafter referred to as TMK) to safeguard the rights of the original custodian of Traditional Knowledge. (hereinafter referred to as TK).

The Imperative for Intellectual Property Protection of Traditional Medicinal Knowledge (TMK)

Indian Traditional Medicines (ITMs) need proper intellectual property rights (IPR) protection because of their unique features. ITMs have evolved over thousands of years and follow set principles making them very different from modern medicine in how they create new ideas and do research. Old research methods work alongside new research and development (R&D) practices. Companies put a lot of time and money into this, including long clinical trials that can take 10-12 years for new formulas, as a big Ayurvedic company points out¹². To encourage more new ideas in ITMs, people think it's key to protect these investments with longer IP rights. The Indian government agrees with this idea. It wants ITMs to protect their new ideas from being stolen and to have access to good raw materials. However, people in the industry also need clear advice on how to use these protections. Although there is no concrete case precedent which deals with need for IP protection of ayurvedic products, the Hon'ble Supreme Court of India in the case of *M/S Indian Medicines Pharmaceuticals Corporation Ltd. vs. Kerala Ayurvedic Co-operative Society Ltd.*¹³, focused on transparency and fair competition in acquiring such products, indirectly supporting a well-regulated market for them.

As TMK, ayurvedic medicines are not given enough protection under the IP framework, there remains high chances of the formulas getting exploited in the market. It gets exploited for misappropriation by third parties, who use the formula of the TMK, without prior consent from

¹¹ Forum on Indian Traditional Medicine (FITM), Research and Information System for Developing Countries (RIS), 'Traditional Medicine and Intellectual Property Rights: Law and Policy Perspectives' <https://fitm.ris.org.in/sites/fitm.ris.org.in/files/Publication/FITM%20Discussion%20Paper%20No-1.pdf> accessed 12 July 2024.

¹² Ravi Prasad, Executive Chairman, Himalaya Drug Company, interviewed in Times of India (New Delhi, 14 January 2012).

¹³ *Civil Appeal No 6693 of 2022.*

the holder of the traditional knowledge and also without giving fair award. TMK is the essence of local communities. It is part of the social and physical environment, therefore the protection of TMK is of paramount importance. For availing the Industrial or commercial benefits, the TK often gets exploited and may lead to misappropriation, which tends to impair loss to the actual custodian of the invention. It is high time to give appropriate protection to TMK. IPR is needed to promote commercialization of TM. Collection of the knowledge can be done through TKDL (Traditional Knowledge Digital Library) and PBR (People's Biodiversity Register)¹⁴. IP rights can also help in Benefit Sharing, contribute to self-determination and will ensure ultimate economic development.

The WHO Global Strategy and plan of action on public health, innovation and intellectual property (2008) recommended that policies on innovation in the field of TK needs to be promoted and encourage research on mechanisms for action and pharmacokinetics of TK. The main objective of the Strategy is to prevent the misappropriation of TK. An adequate patent system with a proper economic background can attract investment in R&D and increase innovation in the TK sector. Members of the World Intellectual Property Organization (WIPO) have finalized a new treaty which shall make it mandatory for patent applicants to disclose the country of origin or the source of genetic resources if the claimed invention is derived from those materials or related traditional knowledge.¹⁵ The International organizations are concerned with giving protection to the TK. Therefore, it is crucial to provide robust legal support to the TMK to protect the rights of the custodians of TK.

Challenges in Granting Patent Protection to Traditional Medicinal Knowledge (TMK)

The idea of 'public domain' in intellectual property rights (IPRs) refers to works and products that IPR doesn't protect letting people use them freely without asking the rights holder. Traditional knowledge (TMK), unlike other types of intellectual property, doesn't recognize this idea right now. Under customary and indigenous laws, like Biological Diversity Act, 2002, TMK protection prevents certain knowledge from being patented and keeps it safe from misuse. However, adding TMK to patent systems might clash with existing laws and lead to people taking advantage of traditional knowledge during and after the patent period. This could

¹⁴ Biological Diversity Rules 2004, r 22(6).

¹⁵ New Patent Pact Offers Extra Shield To Indian Genetic Resources And Traditional Knowledge (The Times of India, 12 July 2024) <https://timesofindia.indiatimes.com/india/new-patent-pact-offers-extra-shield-to-indian-geneticresources-and-traditional-knowledge/articleshow/110427788.cms> accessed 12 July 2024.

potentially impact countries like India which now have a robust IP protection framework in effect¹⁶. Prohibition of discrimination under International agreements like TRIPS creates issues about patenting traditional medicines. It is uncertain for the moment that whether this move would prove beneficial for everyone, including MNCs, or negatively impact local healers. WHO's health plans lean towards modern medicine, so there's not much room for old-school know-how. Also, patents go to one person, not a whole group. With traditional medical knowledge (TMK), both individuals and communities chip in making it hard for TMK to get patent protection. This means we need to think hard about these tricky issues. We must make sure we treat traditional knowledge and protect it in today's world of intellectual property rights.

Mechanisms for safeguarding Traditional Knowledge

- 1. Traditional Knowledge Digital Library (TKDL)** - TKDL is an initiative of India, under the joint collaboration of the Council of Scientific and Industrial Research (CSIR) and Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy (AYUSH), to prevent exploitation and to protect TMK at Patent Offices worldwide.¹⁷ TKDL is a software which is used to convert text in local languages into multiple international languages. Using the Unicode metadata methodology, this software converts the abstract into multiple languages. For example- *Kumari* is converted into *Aloe vera*. TKDL has an inbuilt search interface which gives the full text upon a single search and helps in retrieving all possible information in different languages.¹⁸ The main motto of this tool is to protect TK from misappropriation by third parties. It preserves the benefits of TK, which can be exploited by future generations. The ultimate goal is to preserve the rights of the TMK custodian, being an Individual or a whole community. It also helps the developing countries to extract benefits of granting protection.¹⁹
- 2. Traditional Knowledge Resource Classification (TKRC)** - Earlier, there was no classification system with regards to traditional knowledge (TK) documentation. On

¹⁶ Taubman, Antony. 2007. The public domain and international intellectual property law treaties. Intellectual Property: The Many Faces of the Public Domain. Edward Elgared. 2007. ISBN 978 1 84542 874 7.

¹⁷ Traditional Knowledge Digital Library Unit (TKDL), CSIR, <https://www.csir.res.in/documents/tkdl>.

¹⁸ Shukla DB, 'Synergy of Intellectual Property and Traditional Knowledge: Holy Grail for Protection and Sustainable Future' (2010) 1 Open Conf Proc J 151-6.

¹⁹ World Intellectual Property Organization, *Intellectual Property and Traditional Knowledge* (34 Chemin des Colombettes, P.O. Box 18, CH-1211, Geneva 20, Switzerland) <https://www.wipo.int> accessed 6 June 2011.

the basis of IPC (International Patent Classification), a modern classification was developed. Its main focus is for the development of the medicines in the Indian medicinal system, those are, Ayurveda, Unani, Siddha and Yoga and it is termed as TKRC. The evolution of TKRC has attracted International recognition tied up with IPC. The main objective of TKRC is to spread more awareness of the traditional knowledge systems by using the modern system of Information technology, specifically Web technologies and Internet. It has enabled retrieval of information on traditional knowledge in a scientific manner which can be linked to IPC.

3. Access and Benefit-sharing mechanism - TK involves various forms of unique knowledge which has always a high value attached to it. It can be traced back that the TK has always been associated with threats due to over exploitation, colonization and globalization of different cultures across the globe. Here comes the role of IP, which is to safeguard the TK from getting exploited. Access and Benefit sharing is a way by which genetic resources are explored and used for greater good. The entire mechanism is to utilize genetic resources to give the ultimate benefits to the users. Therefore it denotes a positive protection as it gives the free exploitation of TK along with some authority over it. The Convention on Biodiversity (CBD) has identified the role of TK in promoting its application with prior consent of the holder of TK, which is denoted a Prior Informed consent (PIC) and also through MAT (Mutually Agreed Terms) with the involvement of holder of TK. The participation of ILCs (local communities) is crucial in the circumstances where traditional knowledge associated with genetic resources is being accessed.²⁰

4. Sui Generis - There have been proposals advocating for the establishment of a *sui generis* system specifically tailored for the protection of traditional knowledge. This system is designed to accommodate the unique qualities and requirements of traditional medicinal knowledge, potentially as an alternative or supplement to the current intellectual property rights framework. Inference can be taken from the Plant Variety Act, 2001 which has gained substantial positive feedback due to nuanced and customized approach of dealing with plant variety property in accordance with the socio-economic conditions of India. The *Sui Generis* system mainly aims at prohibiting

²⁰ Convention on Biological Diversity, *Introduction to Access and Benefit-Sharing* (CBD Secretariat 2011) <https://www.cbd.int/abs/infokit/revised/web/all-files-en.pdf> accessed 12 July 2024.

the extraction of any database in which there is a considerable investment in obtaining the data contents. It is defined as something special or unique in nature. The aim of the *Sui generis* system is to preserve traditional knowledge. The ultimate aim of the *Sui Generis* system in India could be achieved by some modification in the existing Intellectual Property rights regime interlinked with TK, policy requirements and taking into account the concept of Prior Informed Consent (PIC) and equitable sharing. Countries like Thailand have adopted a *sui generis* system to protect traditional medical knowledge. Protection and Promotion of Traditional Thai Medicinal Intelligence Act safeguards the "formulas" of traditional Thai drugs and preserves texts on traditional Thai medicine'. Pertaining to *Sui Generis*, the Intellectual Property protection has two forms.

- a. **Positive Protection** - Aims to grant IP Rights over TMK. It helps the society to prevent others or third persons from misappropriating or gaining illegitimate access to TMC or exploiting it for commercial benefits without the necessary component of equitable sharing of the benefits. It also enables proper exploitation of TMC by the community holding the custodian of knowledge.
- b. **Defensive Protection** - This approach does not grant IP rights over TMC but it puts an Injunction over acquiring such rights by third parties. These strategies include the use of documented TMK to invalidate patents on claimed new inventions that are based on such traditional knowledge.²¹

Enhancing existing protection mechanism: The Way Forward

TK protection in Ayurveda entails several new strategies beyond current frameworks. To begin with, digital watermarking can be utilized to identify and track digital copies of Ayurvedic texts in order to trace their origin as well as monitor their use over different platforms. Blockchain technology also provides a decentralized secure way for maintaining a tamper-proof database on Ayurvedic formulations and knowledge that enhances transparency and accountability during dissemination. Community-based certification systems may enable local practitioners to authenticate or validate the genuineness and traditional nature of Ayurvedic knowledge using

²¹ World Intellectual Property Organization, 'Intellectual Property and Traditional Medical Knowledge' (WIPO, 2023) <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-5-6-en-intellectual-property-and-traditional-medicalknowledge.pdf> accessed 12 July 2024.

peer review mechanisms thus preventing misappropriation of this cherished information. The inclusion of Ayurvedic practices into national and international health care systems would ensure that they are acknowledged under health policies thereby enabling protections through regulatory frameworks. Educational outreach programs like workshops, seminars, online courses among others are important for spreading awareness about the value and appropriate utilization of Ayurvedic knowledge among practitioners and the public at large. Lastly, fostering international collaborative agreements could establish kind-of Access and Benefit-sharing mechanisms similar to those designed towards Traditional Knowledge on Traditional Medicines in India's TK system.

Conclusion

In India, the IP protection over Traditional Knowledge (TK) potentially stands in a weak position. People often get a leeway to unfair exploitation of TK for their commercial outcome, without the prior consent of the TK custodian. It is pivotal to give robust legal protection to the holder of the TMK both in electronic and isolated platforms. The existing alternatives to safeguard the interest of TK holders, might not achieve the targeted objective. The traditional knowledge needs to collaborate with modern advancement, in order to eradicate exploitation and protect TK custodian rights.