TRADITIONAL KNOWLEDGE IN MODERN TIMES: AYUSH MEDICINES AND PATENTS IN INDIA

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ABSTRACT

The paper explores the complex intersection of patentability and access to AYUSH (Ayurvedic, Yoga, Unani, Siddha, and Homeopathy) medicines in India, delving into the existing criteria for patenting these traditional remedies and the challenges associated with obtaining such patents. The study then offers a comprehensive analysis of how the grant of patents to AYUSH medicines impacts their availability and affordability. With a significant portion of the Indian population relying on AYUSH medicines for healthcare, the consequences of restricted access are of utmost concern. The paper will conclude by suggesting some measures that could be taken to strike a balance between the need to protect innovation and equal access to basic medicines, which the Indian society has been dependent on for ages.

I. Introduction

In an increasingly interconnected and knowledge-driven world, the intricate web of Intellectual Property Rights (IPR), patents, and Traditional Knowledge (TK) has emerged as a pivotal nexus, serving both as a reservoir of ingenuity and a fulcrum of global intellectual discourse. This symbiosis not only safeguards the wisdom of its creators but also enriches the tapestry of global intellect. It has transcended the realms of legal frameworks and treaties, converging at the crossroads of preservation, protection, and propagation, becoming a sine qua non for the self-sustainability of knowledge custodians, the economic prosperity of knowledge-holders, and a vantage point for competitive business advantage.

Crucially, the promotion of Traditional Knowledge (TK) is no longer a niche concern, but a widely acknowledged imperative, assuming an august role in sustaining the livelihoods and

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preserving the cultures of TK-based communities. As TK burgeons, especially in the domain of traditional medicine (TM), new forms of IPR protection have been galvanized, intensifying the ongoing dialogue on sustainable development, intellectual dynamism, and cultural vitality. However, the convoluted labyrinth of traditional healthcare challenges, intricacies intertwined with IPR in TK, and the multifaceted tapestry of community wisdom collectively present a formidable challenge. It is a challenge that demands a nuanced examination, for it is in the intersection of patentability and access to AYUSH (Ayurvedic, Yoga, Unani, Siddha, and Homeopathy) medicines in India where the intricacies of this predicament unravel. The paper posits that while the patentability of AYUSH medicines in India is essential to protect traditional knowledge and innovations, it has raised pertinent questions regarding access and affordability. A careful balance between intellectual property rights and public health is crucial to secure the future of AYUSH medicines in India.

II. Patentability of Ayurvedic Medicines in India

The fundamental tenet underlying the concept of patents resides in the establishment of incentives for innovation and the conferment of a limited monopoly upon the true and first inventor as a means of recognizing and rewarding the introduction of novel inventions and beneficial innovations that serve the public interest. Concerning the patenting of products rooted in traditional knowledge, there is a string imposed by Section 3(p) of the Indian Patents Act of 1970.[2] Under the purview of Section 3(p) of the Indian Patents Act, 1970, a product is explicitly precluded from being categorized as an invention if it constitutes traditional knowledge or represents an amalgamation or mere duplication of established attributes of components that are traditionally recognized, or part of the prior art.[3] However, any product or process that demonstrates a discernible inventive step, characterized by a discernible technological advancement over the extant body of knowledge, such as an elevation in efficacy, the revelation of new industrial applications, or the introduction of innovations marked by economic significance, is deemed eligible for patent protection as stipulated by the Indian Patents Act.[4] In practice, the rate of patent grants for such inventions is notably low, exemplified by the issuance of only 86 patents out of the 761 patent applications submitted

[2] The Indian Patents Act,1970, No. 39, Acts of Parliament, 1970.
[3] *Id.*
[4] Dr. G. S. Lekha, *Patenting of Siddha Formulations: Scope and Issues,* RESEARCH & REVIEWS: JOURNAL OF AYUSH, Aug. 2012, at 50, 52.

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over a three-year period in India spanning from 2019 to 2022.[5] AYUSH drugs, which are developed from pre-existing traditional knowledge or prior art, are generally confronted with significant barriers to obtaining patent protection, largely due to the factors addressed next.

Firstly, a significant portion of Ayurvedic medicines consists of established formulations that do not possess a distinctive inventive step, as the knowledge underpinning the development of those products has been existent and passed on in the society for an extensive duration.[6] Secondarily, in instances where specific aspects of traditional knowledge are publicised to counteract biopiracy, exemplified by initiatives like the creation of the Traditional Knowledge Digital Library (TKDL), these disclosures, even if they were not formerly available as part of the prior art, fall within the public domain, and consequently, lack the hallmark of inventive step.[7] Another challenge in the realm of traditional knowledge's patenting revolves around the convictions held by local communities. They firmly believe that documenting traditional knowledge which is passed down through generations within their community or among their familial circles, typically via an oral tradition, devoid of written records, may be construed as an act of exploiting this invaluable wisdom.[8] It is vital to acknowledge that traditional knowledge represents the shared wisdom of these communities, vehemently opposing any notion of individual ownership.[9] Moreover, there are stark differences in patent regimes around the globe which might make it difficult to get a global patent for AYUSH medicines, especially in the non – member countries when it comes to agreements like TRIPS.

Although the Indian patent framework is inherently restrictive and incongruous with the notion of granting patents for innovations stemming from Traditional Knowledge (TK) as a means of safeguarding local communities, there is a discernible trend towards Westernization of TK. This shift is affording prominent Western industry players the opportunity to secure patents on TK-derived inventions, thereby enabling them to exploit these innovations globally. This, in turn, restricts the availability and access of such medicines to the Indian local community, who originally pioneered these inventions. Although patenting TK will have some serious effects such as limited access of local communities to the patented product, exploitation by capitalist

[5] *761 Ayurveda patents filed in 3 years, only 86 granted,* THE TRIBUNE (July 22, 2022, 6:19 PM), https://www.tribuneindia.com/news/nation/761-ayurveda-patents-filed-in-3-years-only-86-granted-414759
[6] *Patent and IPR Ayurveda Perspective,* AYUSOFT (Mar. 8, 2021, 11:25 AM), https://ayusoft.ayush.gov.in/patent-and-ipr-ayurveda-perspective/
[7] *Id.*
[8] Sunita K Sreedharan, *Bridging Time and Tide- Traditional Knowledge in the 21st Century,* JIPR , MAR. 2010, at 147, 147.
[9] Convention on Biological Diversity, *Art.* 8(j).

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entities from the West further will result results in the erosion of sovereignty and privileges concerning indigenous products,[10] especially given that traditional knowledge forms the foundation of practice for a considerable number of non-capitalist practitioners in developing countries, such as India, where many individuals derive their livelihoods from such practices.[11] At this juncture, it is imperative to acknowledge the commendable efforts of the Indian government in establishing the Traditional Knowledge Digital Library (TKDL) as a repository for prior art. Nonetheless, there is a prevailing argument that this step, while laudable, falls short of adequately protecting traditional knowledge. Some of the criticisms of the TKDL which highlight the need for a more comprehensive patent protection regime are as follows.

- Indigenous communities strongly oppose the notion of classifying their traditional knowledge as property or a commodity. They regard this knowledge as a gift from nature, and they firmly reject the idea of its alienation to individuals or organizations.[12] Traditional knowledge, as a natural endowment, remains intertwined with both nature and the local community that has safeguarded it. Indigenous peoples advocate for a different approach; rather than imposing foreign legal constructs, they seek protection that promotes self-sufficiency and the ability to thrive independently.[13] Their aspiration centres around securing the right to self-determination. As a consequence, there is a possibility that the patent examination office falls short in comprehending the intricacies of TK and an unfair patent is granted.[14]
- A notable procedural challenge lies in the inadequate training of many patent examiners to recognize Traditional Knowledge (TK) as prior art. This issue is exemplified by a case in which the United States Patent and Trademark Office (USPTO) granted a patent for the use of Aloe Vera in treating dry eyes, with the sole novel aspect being the use of chlorinated water instead of clean water.[15] This instance underscores the examiner's lack of competence. While it is a requirement under the agreement granting a patent office access to the Traditional Knowledge Digital Library (TKDL) that the Council of Scientific and Industrial Research (CSIR) trains patent examiners to use TKDL search

[10] *Protecting India's Traditional Knowledge,* WIPO (June 2011) https://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html
[11] India Patent Application No. 31/Del/2008, 07/08/2009.
[12] S Sharma, *Traditional Knowledge Digital Library: "A Silver Bullet" In the war against biopiracy?* , THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW, 2017, at 214, 214-231.
[13] Whitt L, Science, *Colonialism, and Indigenous Peoples*, CAMBRIDGE UNIVERSITY PRESS, 2009, at 136, 136-156.
[14] *Supra* n. 11.
[15] USPTO Patent Full Text and Image Database, United States Patent & Trademark Office.

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tools and examination processes,[16] another procedural concern is the significant discretion vested in patent examiners when assessing patent claims.[17] Research has indicated that experienced examiners are more likely to grant patents without thoroughly addressing prior art, resulting in higher patent grant rates.[18] Moreover, Reference to database by patent examiner would be voluntary and patent examiners in member countries would have no obligation to consider this information in their prior art searches.

- Moreover, Access to the Traditional Knowledge Digital Library (TKDL) is limited to a mere nine patent offices globally,[19] and the process for patents via TKDL is significantly protracted, often exceeding the seven-year duration stipulated for pre-TKDL applications, with cases dating back to 2008 still awaiting finalization.[20]
- A significant legal challenge pertains to the absence of a consistent interpretation of 'prior art,' resulting in the non-recognition of data contained in the Traditional Knowledge Digital Library (TKDL) by the United States Patent Office.[21] This issue stems from the coexistence of two distinct standards for defining prior art in the United States: the Pre-America Invents Act standard and the Post-America Invents Act standard. Notably, the former standard does not permit the citation of TKDL entries as prior art. It's worth noting that the complete transition to the Post-America Invents Act standard is not anticipated until March 15, 2034.

Nonetheless, it is imperative not to summarily dismiss the concept of TKDL, as it inherently endeavours to safeguard traditional knowledge from commodification. Rather than outright rejection, a more constructive approach involves addressing its shortcomings. While indigenous communities hold profound moral values and sentiments regarding traditional

[16] V K Gupta, *The Functioning of the TKDL, Co-operation with International Patent Offices and Security & Access Consideration,* (Mar 22, 2011), https://www.tkdl.res.in/TKDL/Conference/pdf_files/VKGupta_INDIA_2.pdf.
[17] I M Cockburn, S Kortum & S Stern, *Are all patent examiners equal? The impact of characteristics on patent statistics and litigation outcomes,* NATIONAL BUREAU OF ECONOMIC RESEARCH, June 2002, at 1, 12.
[18] M A Lemley & B N Sampat, *Examiner characteristics and patent office outcomes,*94 THE REVIEW OF ECONOMICS AND STATISTICS, 817, 817 – 818 (2012).
[19] Deekshitha Ganesan, *Sui generis is the answer: positive protection of traditional knowledge in India,* 11 JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE, 49, 53 (2016).
[20] P H Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions,*15 FEDERAL CIRCUIT BAR JOURNAL, 679, 685 (2006).
[21] *Supra* n. 11.

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knowledge, it is crucial for them to recognize that TKDL's intent is rooted in assistance and preservation.

III. Impact on Availability and Affordability

The Traditional Healing method is one of the fastest growing areas of healthcare system in India due to the recent trend of growing health awareness. Ayurveda manufacturers believe that patent is the most relevant item to explore the market for Ayurvedic medicines. Patents have strengthened innovations in the field of Ayurveda and have helped identify new uses for medicines.[22] infact, the most common arguments from the manufacturers of ayurveda is that their invention contains an inventive step as they have developed a composition with 'specific herbs' for 'specific diseases'. This argument does not stand ground as merely using herbs do not constitute a part of traditional medicine in the first place.[23] Ayurveda is a well-known system of healthcare and is the most preferred option for a majority of Indians to resort to and therefore it is argued that granting of patents will not only help in commercialisation and monopoly creation of AYUSH medicines in India but around the global and will thus restrict access and affordability. It is prima facie established that this will in turn go against the very basis of community knowledge sharing and healing aspect of traditional knowledge. The free use of this knowledge will be hampered to cater to the interests of a few power players in the market. Few instances wherein big corporations have been successful in getting a patent for AYUSH drugs are outlined below, although some of them have been challenged on the basis of TKDL and subsequently revoked, the rest remain concentrated in the hands of the monopolistic abusers.

- The first instance is that of the patenting of Acorus Calamus along with Brahmi herb by an application filed in the USPTO for improving overall mental performance in children and adults.[24] This herb has been used in India to treat neurological disorders since ages[25] and is usually given along with honey to children in many Indian

[22] Edward A. Pisacreta & Seth H. Ostrow, *Intellectual property licensing : Forms and Analysis*, NEW YORK: LAW JOURNAL SEMINARS, 2013.
[23] Indian Patent Application No. 31/DEL/2008.
[24] US Patent publication No. 20030157201.
[25] K. S. Murugesha Mudhaliar., *Gunapadam Mooligai Vaguppu*, 1 INDIAN MEDICINE AND HOMEOPATHY. 788, 788–789 (2021).

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households.[26] Although there has been no protest against the granting of this patent, it is evident that there is no novelty or inventive step involved in the patent application. This application is presently abandoned.

- The second is of the patenting of shell of mollusk sps like oyster which is used as a remedy for acne, ulcers and dermatitis when mixed with lemon and made into a paste.[27] This medicine has been popularly known as bhasma in India and has been used to treat skin related conditions for ages. A US patent has claimed this formulation into a cometic product by mixing it with the citric acid contained in fruits.[28] The claim also says that this composition has skin healing properties and has also claimed a specific right over the shell. It is pertinent that this composition has been well known and traditionally used in India well before this claim was registered and there should be no grant of patent.
- The third instance is of patenting of Shilajit which is considered a wonder drug for the treatment of a wide range of therapeutic and nutraceutical applications.[29] An application was filed in the USPTO which claimed a composition of shilajit used in a multivitamin preparation.[30] This was meant to be consumed in an oral form. Clearly, there is no inventive step involved here as well. This is presently in the public domain as the patent is expired, but the consequences of granting of such a patent today would be hard to determine.
- The fourth instance is the patenting of fenugreek seeds combined with bile juice from animals for the treatment of diabetes. This medicine has been used in India since 1550 BC and the claim in USPTO for this drug is absolutely unacceptable. This patent has expired as recent as in 2021.
- The fifth instance is the most famous instance of the claim of patent on turmeric. Turmeric has been used in Indian households for ages for its various properties such as a medicine, blood purifier and in treating common cold. The patent application claimed the use of turmeric powder and its administration both orally as well as a topical for wound healing. The patent claimed an exclusive right to sell and distribute the said substance. Although the opposition by ICMR finally led to the revocation of this patent,

[26] Pulok Kumar Mukherjee, Venkatesan Kumar, Mainak Mal &Peter J. Houghton, *Acorus calamus.: Scientific Validation of Ayurvedic Tradition from Natural Resources,* 45 TAYLOR & FRANCIS ONLINE, 651, 651-666 (2007).
[27] *Supra* n 3.
[28] US Patent publication No. 4393045.
[29] K.M. NANKARNI, INDIAN MATERIA MEDICA VOL.I, 23-32, (Bombay Popular Prakashan, 1908).
[30] US Patent publication No. 5405613.

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it was extremely hard to find documented evidence for the usage of turmeric which has been present for centuries in India

- The next instance is with respect to the patenting of neem in the USA and the European Patent Office. The patent application claimed that neem is used for controlling the growth of fungi on plants. It is no surprise that neem has been used in India for ages for various purposes from treating diseases to using it as a food item. Once again a legal opposition was filed by India in this case and the patent was revoked both in the Europe and the USA protecting India's traditional knowledge.
- Lastly even a patent claim for use of jamun plant as an anti - diabetic medicine was granted by the USPTO in 2004.[31] This patent was challenged by the Indian government in 2008 and subsequently revoked after it had been recognised that this composition has been used in Indian traditional medicine for centuries.

IV. Conclusion and Suggestions

Having established the significant reliance on traditional medicine in India, it is of utmost importance to safeguard these traditional remedies from exploitation by foreign industry giants while maintaining affordability and accessibility within our nation. As we have previously examined the limitations of TKDL, the introduction of an alternative approach becomes imperative. A sui generis system for patenting traditional knowledge should be implemented. This sui generis system would represent a departure from the existing patent framework and be meticulously tailored to protect traditional knowledge and practices. Such a system holds the potential to prevent unauthorized appropriation of traditional knowledge by external entities, ensuring that the benefits derived from this knowledge are equitably shared with the communities that have cultivated and preserved it across generations.[32]

The WIPO negotiations regarding Traditional Knowledge (TK) have aimed to formulate a sui generis protection mechanism.[33] Certain countries have effectively embraced a combined approach that encompasses both defensive and affirmative protection measures.[34] It is suggested that the best suited sui generis model for India would be to adopt the Peruvian model of protection of TK. The Peruvian model establishes that individual ownership of TK is

[31] US Patent publication No. 20090061066A1.
[32] *Supra* n 5.
[33] *Supra* n 18.
[34] SE Clark, Manuel Ruiz & Isabel Lapeña, *The Protection of Traditional Knowledge in Peru: A Comparative Perspective,*3 GLOBAL STUDIES LAW REVIEW, 755, 763 – 766 (2004).

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impermissible, requiring indigenous communities to collectively exercise their rights through a representative organization.[35] This collective approach serves to safeguard their interests and allows them to establish their own priorities. Moreover, communities can grant prior and informed consent to licensing agreements, provided that these agreements facilitate equitable benefit-sharing.[36] of all indigenous communities, financing various development projects.[37]

The Peruvian approach consolidates various aspects of Traditional Knowledge (TK) protection under a unified legal framework. It acknowledges the collective nature of TK rights and ensures the availability of crucial knowledge for technological innovation, contingent upon the consent of indigenous communities.[38] India's TKDL and its existing TK protection framework appear to have shared similar initial objectives. To fortify the existing protection mechanism and address the gap associated with oral and undocumented TK, India could consider emulating the Peruvian model. Introducing confidential registers for documenting TK that indigenous communities prefer to withhold from immediate public disclosure would enable them to share this knowledge through contractual arrangements with prior informed consent. By augmenting the current protective framework with legislation specifically tailored for TK, which explicitly acknowledges the rights of indigenous communities to license their TK through representative organizations, India can strike a judicious balance between affirmative and defensive protection.

[35] *Id.*
[36] T Lopez Romero, *Sui Generis Systems for Protection of Traditional Knowledge*, INT'L L REV, 301, 329 (2005)..
[37] *Supra* n 35 at 786.
[38] *Supra* n 35.

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