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Indian Knowledge Systems and Traditional Knowledge: Exploring the Unexplored IP Dimensions in AYUSH

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Traditional knowledge in India exists deeply throughout its Ayurveda and Yoga along with Unani and Siddha and Homeopathic systems which make up the AYUSH healthcare network. Many serious intellectual property issues limit how much the Indian medical system contributes to global healthcare through biopiracy events combined with weak legal safeguards and conflicting IP regulations from other nations. The enhancement of IP dimensions for AYUSH represents a vital requirement for developing global acceptance together with fair distribution benefits and defence against multinational company exploitation.

The authors have investigated the evolving relationship linking AYUSH and intellectual property rights (IPR) with a special emphasis on insufficient legal frameworks and the demand for an effective protection framework for India's traditional medical knowledge. This paper has targeted unexplored intellectual property dimensions of AYUSH along with finding the flaws in the current legal system following the TRIPS agreement along with difficulties faced when foreign entities acquire patent on traditional Indian medicine. Towards the end, the paper suggests sui generis system and frameworks that are community centric for providing protective measures and conserving India's traditional knowledge.

Keywords: AYUSH, Biodiversity, Traditional Knowledge, Biopiracy, Legal Measures

Traditional Knowledge in India

India is a country rich in cultural heritage, also known as traditional knowledge (TK) developed through oral traditions, textual writings and practices among various communities. The knowledge has been solidified by different modes in form of medicines, art and craft or agriculture that added value to the economy of the country.[1] Out of all these, the AYUSH system of medicines, which encompasses Ayurveda, Yoga, Unani, Siddha, and Homeopathy, stands out as a distinct form of healthcare, which focuses on holistic and preventive mechanism.[2]

Traditional knowledge is not a static bank of wisdom from the past, but a dynamic system much interwoven with biodiversity, native customs and socio-cultural practices. TK is passed down from community to community and does not have to rely on modern scientific methods, like the empirical validation and standardization, as it places emphasis on years of experience and natural formulations. Still, this very quality of TK, its unrecorded and self-driven nature is what makes it weak to be exploited and misappropriated.[3]

In India, there have been numerous cases where indigenous medicinal practices have been patented illegally by foreign organizations leading to instances of biopiracy and misappropriation. The famous examples of neem patent disputes and Turmeric patents for wound healing highlight the efforts that must be made to secure Indian TK using legal mechanisms of protection and IP.[4] Although India has taken efforts to protect its TK through the Traditional Knowledge Digital Library and the Biological Diversity Act, 2002, it still lacks comprehensive and enforceable IP protection for systems of traditional medicine like AYUSH.[5]

This paper seeks to address this gap by analysing the unexplored intellectual property dimensions of AYUSH, particularly the legal, ethical, and governance challenges that arise when traditional medical knowledge interacts with modern intellectual property regimes.

The Importance of AYUSH in Indian Healthcare Systems

AYUSH Healthcare System provides integrated approaches to health care that are traditional in nature. Thetherapeutic practices from AYUSH systems

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introduce a new dimension to healing as they not only treat medical conditions with modern medicine, but they also emphasize the prevention of illness and promotion of a balanced physical and mental state. Practitioners of AYUSH follow and rely on different unifying theories which determine how various modalities of healing will be used.[6]

Ayurveda is defined as the life science that functions on dosha theory (Vata, Pitta, Kapha) and seeks balance in the body by using phytotherapy and diet with lifestyle management. Through asanas, pranayama, and meditation practiced with yamas and niyamas, yoga provides a holistic system of physical and mental well-being. Unani Medicine, a Greco-Arabic heritage, bases its treatment on the restoration of balance among the blood, phlegm, yellow bile, and black bile. Siddha Medicine blends spiritual healing with herbal and mineral medicines, as well as alchemical techniques, to heal the people of Tamil Nadu.[7] The practice of Homeopathy is categorized under Indian traditional medicine even though it originated in Europe because of the highly diluted cures associated with it.[8]

The approach to health with the acronym AYUSH has kept its primary position within the Indian health policy because of the growing global interest in natural and integrative forms of treatment. Alongside the standardization efforts, the Indian government has established supportive networks through the Ministry of AYUSH, which funded research initiatives. The popularity of AYUSH systems of medicine soared during the COVID-19 pandemic when they were perceived as economical public health interventions capable of enhancing immunity and mental health.[6]

Despite these improvements, there remains a gap in the acceptance of AYUSH practice and law, scientific corroboration, and coverage with existing intellectual property legislation. The scope of unprotected intellectual property is so large, that multinational companies and foreign researchers can freely exploit these medical assets as many therapies and medical patents exist. The challenge lies in deciding how to secure traditional medical knowledge in a way that makes it available to those communities who have conserved it for countless generations.[9]

The Paradox of Protection and Ownership

The AYUSH system (Ayurveda, Yoga, Unani, Siddha, and Homeopathy) is built upon centuries of rich cultural heritage and collective community knowledge.[10] Because these traditional formulations exist largely in the public domain or ethnobiological jurisdiction, they disrupt contemporary intellectual property (IP) systems, which prioritize individual ownership and Western legal concepts.[11]

The assets of indigenous knowledge have become more difficult to protect under the TRIPS agreement of the WTO. The global standards for the protection of intellectual property established by the TRIPS agreement do not adequately protect traditional IP knowledge for its living community holders.[12] The absence of such permission enables multinational companies to patent ethnomedicinal medicines formulated by primary or indigenous communities.[13]

The issues relate to who owns and who can access the benefits that come from it. Attention to AYUSH as a distinct system of medicine gives rise to traditional pharmaceutical products that undergo several rounds of patenting, which then become difficult to protect within modern intellectual property systems because the IP systems within which AYUSH formulations lie are in public or regional culture domains.[10] This creates a paradox.

(i) The open availability of AYUSH knowledge poses a risk for uncontrolled commercial exploitation by foreigners without proper attribution or compensation being made to the indigenous groups.

(ii) Using patents to Monetize AYUSH knowledge would deny access to its traditional users who have maintained the practices over many generations.

In the context of WTO, the TRIPS agreement makes the situation much harder in terms of protecting these traditional knowledge assets. The international standards for Intellectual property protection accepted by TRIPS and the absence of effective mechanisms to protect traditional community-based knowledge dooms it to exploitation. The absence of consent allows multinational companies to patent traditional medicinal formulations from communities to which they were originally developed by the communities themselves.[14]

Indian Knowledge Systems and Traditional Medical Practices

Historical Background of Indian Medical Systems (Ayurveda, Yoga, Unani, Siddha, Homeopathy)

The traditional medical systems of India have always existed for thousands of years, developed due

to the integration of cultural and spiritual elements along with philosophy. Diverse culture such as Vedic civilization with ancient literature and local folk medicine along with foreign medicine created what is referred to as the Indian Knowledge Systems (IKS) integrated with medicine.[15]AYUSH medical systems, which comprises Ayurveda, Yoga, Unani, Siddha, Homeopathy, each have their unique features and processes, yet together form a single holistic approach to traditional knowledge and scientific inquiry.

Ayurveda: The Science of Life

Ayurveda is believed to be one of the oldest systems of medicine in the world as it started during the Atharvaveda era (1200 BCE) and kept on advancing during the period of the two great books Charaka Samhita and Sushruta Samhita. The regulation of the human physiology involves the three doshas Vata (air), Pitta (fire) and Kapha (water) as stated by Ayurveda.[16] The three doshas need to be in the right balance for good health, and any imbalance will lead to sickness. Ayurveda teaches that it is possible to prevent diseases through healthy diets and practices like yogas and performing daily activities called dinacharya.[17] Combining herbal treatment with the detoxification processes called Panchakarma and other methods, the approach to medicine in Ayurveda is holistic in nature. Ayurvedic Rasayana therapy is aimed at prolonging an individual's lifespan while improving their health and vigor.[18]

The recent global resurgence of Ayurveda has motivated researchers to look into its principles and study various concoctions for their therapeutic effects especially in the management of metabolic disease, autoimmune disorders, and psychoneurosis.[19]

Yoga: The Union of Body, Mind, and Spirit

Physical postures (asanas) represent only the well-known aspect of Yoga because this Indian discipline functions as an organized spiritual method that combines therapeutic elements. The Yoga Sutras of Patanjali (c. 300 BCE) presents the philosophical and meditative part of yoga alongside the physical aspect which Hatha Yoga Pradipika (15th century CE) highlights. Yoga defines its spiritual path using eight stages known as Ashtanga Yoga comprising the following elements:[20]

(i) Yama (ethical discipline)
(ii) Niyama (self-discipline)
(iii) Asana (postures)
(iv) Pranayama (breath control)
(v) Pratyahara (withdrawal of senses)
(vi) Dharana (concentration)
(vii) Dhyana (meditation)
(viii) Samadhi (absorption or enlightenment)

Modern medical research supports yoga as a clinical method to control stress, protect the heart and protect joints and treat ongoing diseases.

Unani Medicine: The Greco-Arabic Healing Tradition

Unani medicine traces its roots to ancient Greek traditions, with significant contributions from renowned physicians such as Hippocrates (460–370 BCE) and Galen (129–200 CE). Over time, it evolved further under Persian and Arab influences, particularly through the works of scholars like Avicenna (Ibn Sina, 980–1037 CE). India was introduced to this system during the Delhi Sultanate in the 13th century, and soon it becamevery crucial part of traditional healthcare.[21]The four basic humors (Akhlat) of Unani medicine are blood, phlegm, yellow bile, and black bile. It emphasizes maintaining overall health and restoring physiological balance. It focuses on restoring balance through:[22]

- Ilaj bil Ghiza (diet therapy)
- Ilaj bil Dawa (herbal medicine)
- Ilaj bil Tadbeer (regimental therapy, including cupping and massage)
- Ilaj bil Yad (surgical intervention)

Unani medicine can now treat skin disorder, gastrointestinal issues and also several lifestyle issues.

Siddha Medicine: The Dravidian System of Healing

Siddha medicine is one of the oldest systems from South India, attributed to the Siddhars—ancient spiritual healers and scholars. Siddha texts, mainly written in Tamil, highlight the use of metals, minerals, and plant-based drugs. The system emphasizes:[23]

- The balance of three humors (Vali, Azhal, Iyyam), like Ayurveda.
- Kayakalpa (rejuvenation therapies) to prevent aging.
- Alchemical preparations (Muppu) used in treating chronic illnesses.

Siddha medicine is widely practiced in Tamil Nadu and Sri Lanka and is particularly known for its herbo-mineral formulations, external therapies, and lifestyle amendments.

Homeopathy: The European Alternative Integrated into India

Homeopathy is very popular in India, and it was started by German physician Samuel Hahnemann in the late 18th century (1796). The method is popular

because of its non-invasive and holistic nature. It is used to stimulate natural healing process of the body based on the concept of *like cures like* (foundational principle of Homeopathy). Today, India is one of the largest users of homoeopathy. Overall, there are 200 million people worldwide trusting homoeopathy.[24]

Contributions of AYUSH to Global Health

The global recognition of natural and holistic healing systems has led to the increasing acceptance of AYUSH. Ayurvedic herbal formulations such as Ashwagandha and Turmeric have gained international recognition for their anti-inflammatory and immunomodulatory properties. Yoga has received a worldwide adoption because of its therapeutic results in stress relief, hypertension, mental health, and other health benefits. It has also got recognition by global organisations like WHO and United Nations. Unani and Siddha treatments are much used in chronic conditions like Gastrointestinal issues, metabolic disorder, skin diseases.[25] They have proved to be an alternative for modern medicines. Homeopathy has also received recognition worldwide, including countries like Germany, France and the UK. Many countries practice homoeopathy along with conventional medicines.[26]

The inclusion of AYUSH practices in WHO's Traditional Medicine Strategy, the establishment of the WHO Global Centre for Traditional Medicine (GCTM) in Jamnagar (2022), and the Gujarat Declaration (2023) have further authenticated their relevance in global healthcare policies and practices.

Comparison with Other Traditional Medical Systems (TCM, Indigenous Healing Practices)

Traditional Chinese Medicine (TCM) v *AYUSH*

A comparative analysis reveals that both systems emphasise physiological balance: Qi in TCM and Doshas in Ayurveda. Acupuncture, herbal medicine, and Qigong are used in TCM, while dietary changes, yoga and unique herbs are used in Ayurveda. TCM is widely incorporated in the global healthcare markets. It has been completely commercialised while Ayurveda is still in the phase of regulatory and IP challenges.[27]

Indigenous Healing Practices v *AYUSH*

Indigenous medical systems, such as African, Amazonian, and Native American medicine, focus on spiritual and ecological connections similar to Ayurveda and Siddha. Unlike AYUSH, many indigenous practices remain undocumented and at risk of biopiracy. India's Traditional Knowledge Digital Library (TKDL) serves as a model for other nations to prevent the patenting of indigenous knowledge by foreign entities.[28]

Legal Framework Governing Traditional Knowledge in India

Traditional Knowledge in India maintains substantial cultural worth in addition to medical and economic value for the AYUSH field which includes practices of Ayurveda, Yoga, Unani, Siddha, and Homeopathy. The protection of traditional medical knowledge faces intense resistance because such measures have raised concerns about biopiracy and IP safeguards that are insufficient to prevent misappropriation. India has established a complete set of protective legal mechanisms to defend traditional knowledge through fair benefit-sharing systems.[29] The recovery and protection of AYUSH knowledge through Biological Diversity Act 2002, as well as Traditional Knowledge Digital Library (TKDL) and the Indian Patent Act and multiple Intellectual Property law aspects including copyrights, trademarks, and geographical indications (GIs) form a vital combination.

Biological Diversity Act, 2002 and Access and Benefit Sharing (ABS) Mechanisms

Overview of the Biological Diversity Act, 2002

The Biological Diversity Act of 2002 established itself as a response to India's CBD obligations set forth in the Convention on Biological Diversity which became effective in 1992 to achieve three main objectives:[30] to conserve biological diversity; to build systems that promote sustainable utilization of biological resources, and to enact laws that enable fair distributionof benefits that stem from biological resources together with their traditional knowledge.[31]

India's Biological Diversity Act operates as an essential regulatory tool because it controls genetic resource and traditional knowledge access together with unauthorized exploitation in a nation known for both biological diversity abundance and deep traditional medicinal understanding.[32]

Access and Benefit Sharing (ABS) Mechanisms

The Access and Benefit Sharing mechanism through the Biodiversity Act of 2002 provides measures to stop biopiracy and establish fair methods for sharing profits generated from commercial utilization of traditional medical expertise. The Act

establishes[32]National Biodiversity Authority (NBA) thatregulates access to Indian biological resources, especially for foreign entities; the Biodiversity Boards that operate at state levels through their role of governing biodiversity management.The Act also incorporates Biodiversity Management Committees (BMCs) to maintain People's Biodiversity Registers (PBRs) for recording and protecting Traditional Knowledge at the local level. It also guarantees that users of traditional knowledge commit to fair compensation through ABS Agreements. Furthermore, the Biological Diversity (Amendment) Act, 2023, recently modified this framework by exempting registered AYUSH practitioners and codified traditional knowledge from prior intimation to SBBs, sparking active national debate on benefit-sharing compliance.

Challenges in ABS Implementation

Despite having a good intent, the ABS framework faces many issues. There is lack of awareness amongst the traditional knowledge holders about their rights given under the act. The granting of approvals for research and commercial use face bureaucratic delays. The enforcement mechanism remains vulnerable and biopiracy continues. These issues represent major challenges.[33]

Traditional Knowledge Digital Library (TKDL) and Its Role

Background and Establishment

The Traditional Knowledge Digital Library (TKDL) was a measure by the Indian government to protect misappropriation of traditional medicinal knowledge through patenting. Some major high-profile biopiracy cases were:[34] Turmeric (1995): A US patent was granted for the wound-healing properties of turmeric, later revoked after India proved its prior traditional use; Neem (2000): A European patent for neem's antifungal properties was revoked after India demonstrated its historical medicinal usage; and Basmati Rice (1997): A US company attempted to patent Basmati rice varieties, sparking global controversy.

To counter such threats, TKDL was launched in 2001 as a collaborative effort between the Council of Scientific and Industrial Research (CSIR) and the Ministry of AYUSH.

How TKDL Works

India's traditional medicine knowledge is documented in the digital database called as TKDL. It is a comprehensive data of compilation of over 4.5 lakh formulation from the ancient texts. It is multilingual and has been taken from texts like Charaka Samhita, Sushruta Samhita and Unani manuscripts.To prevent misappropriation through foreign patent claims, this digital database is translated into five international languages (English, French, German, Japanese, and Spanish).Direct access agreements have also been established with major international patent offices to ensure thorough prior art searches.[34]

Impact of TKDL on AYUSH Protection

The Traditional Knowledge Digital Library (TKDL) has had a profound impact on the protection of AYUSH by significantly strengthening India's legal standing against biopiracy. Through its direct interventions, the TKDL has successfully led to the rejection of over 230 patent applications worldwide. Furthermore, its implementation has changed global intellectual property procedures, as international patent office now routinely conduct prior art searches within the TKDL database before granting new patents, ensuring that traditional Indian medicinal formulations are proactively safeguarded from unauthorized claims and exploitation.

Indian Patent Act and Its Limitations Concerning AYUSH

Provisions for Traditional Knowledge in the Indian Patent Act

The Indian Patent Act, 1970, as amended in 2005, incorporates several safeguards against patenting traditional knowledge. Section 3(p) explicitly states that "traditional knowledge or any aggregation or duplication of known properties of traditionally known components" cannot be patented. There is also a requirement for Disclosure of Source and Geographical Origin which prevents unauthorised claims by making sure that every invention derived from biological resources discloses its source.[35]

Limitations of the Patent Act for AYUSH

There are several gaps in implementation in spite of the safeguards provided as most traditional formulations are not codified and hence, there are loopholes in application of patent. Many AYUSH formulations do not meet the requirements of novelty and inventive step criteria under the patent law, unlike the modern pharmaceuticals and hence there is lack of patent protection for AYUSH. There are also challenges in enforcing patent rights for

AYUSH-based pharmaceuticals in foreign jurisdictions.[36]

Protection of Traditional Knowledge Under Copyright, Trademarks, and GI Laws

Copyright and Traditional Knowledge

Copyright laws protect literary, artistic, and musical works, but traditional medicinal knowledge does not always fit within these categories.

Nevertheless, Ayurvedic manuscripts and other texts that document traditional medicine may be protected by these laws.[35]

Trademark Protection for AYUSH

1 Many AYUSH brands rely on trademark protection for branding and commercial identity.
2 Examples include Himalaya, Patanjali, and Dabur, which have secured trademarks for their formulations and branding elements.

Challenges

1 Risk of misappropriation by companies registering generic Ayurvedic names as trademarks.
2 Absence of acknowledgement of community-based ownership of traditional knowledge.[37]

Geographical Indications (GI) and AYUSH

Under the Geographical Indications (GI) Act of 1999, AYUSH products that are intrinsically linked to specific geographic regions can be granted legal protection.[38] Utilizing this framework offers several strategic advantages, primarily because it confirms economic benefits for local communities, effectively prevents unauthorized commercial usage, and enhances the worldwide branding of AYUSH-related products. Despite these positive aspects, applying GI to traditional medicine presents notable limitations. Specifically, there are inherent difficulties in defining Geographical Indications for complex medicinal formulations, which are further compounded by a lack of enforcement mechanisms in foreign jurisdictions to uphold these protections globally.

International IP Regime and Its Impact on AYUSH

The worldwide intellectual property system determines handling methods for traditional knowledge (TK) such as the comprehensive AYUSH practice of Ayurveda and other practices. The international agreements including TRIPS Agreement and Convention on Biological Diversity with World Intellectual Property Organization (WIPO) initiatives give protection to TK but create major difficulties. AYUSH faces challenges due to international mechanisms concerning traditional knowledge protection as this part evaluates their effect on AYUSH together with different biopiracy cases affecting Indian traditions and points out global IP framework weaknesses for safeguarding Indian medical heritage.[39]

TRIPS Agreement and Traditional Knowledge

Understanding TRIPS and Its Impact on AYUSH

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), established under the World Trade Organization (WTO) in 1995, sets minimum IP protection standards that member countries must implement. The TRIPS Agreement primarily focuses on patents, trademarks, copyrights, and trade secrets, making it ill-suited for protecting traditional medicinal knowledge, including AYUSH.[40]

Key TRIPS Provisions Relevant to Traditional Knowledge

(i) Article 27.3(b) allows countries to exclude plants and animals from patentability but mandates protection for microorganisms, biotechnological processes, and plant varieties.
(ii) Patentability Requirements (Novelty, Inventive Step, Industrial Applicability): Traditional medicinal formulations often fail to meet these criteria since they are publicly known and historically used, making them vulnerable to misappropriation.
(iii) Flexibilities Under TRIPS: Countries can adopt measures to protect public health and traditional knowledge, but enforcement mechanisms remain weak.[41]

Challenges TRIPS Poses for AYUSH

Biopiracy and patent misuse remain significant concernsas TRIPS lacks explicit provisions prevention the patenting ofderivatives or minormodification of traditional knowledge. TRIPS fails to recognize community-based rights, as it places primary emphasis on individual and corporate ownership. Another major challenge is the enforcement issues, it is very difficult for countries like India in challenging illegitimate patents granted in foreign jurisdiction.[42]

Although TRIPS mandates some level of traditional knowledge protection, its commercial and

Western-centricapproach makes it insufficient for fully safeguarding AYUSH.

Case Studies of Biopiracy (Neem, Turmeric, Basmati, etc.)

Neem (Azadirachta indica)

Neem has been known for centuries to aid in anti-bacterial antifungal and insecticidal issues. It is not just medicinal, but also a sacred plant in India. However, a patent was granted to WR Grace, a US based company by European Patent Office for an antifungal extract from Neem.

A critical flaw in the patent grant was its failure to acknowledge established prior art, specifically the centuries-old traditional usage by Indian framersand Ayurvedic practitioners have been using Neem for centuries for similar purposes. This resulted in a legal battle and in 2000 India successfully revoked the patent and also proved that Neem's medicinal use was traditional knowledge and not an invention.[43]

Turmeric (Curcuma longa)

Turmeric is a major compound in Ayurveda that has been used for years in healing wounds, boosting immunity, and for anti-inflammatory treatments. However, the problem was when in 1995, there were two US based researchers obtained patent of the wound healing properties of turmeric from United States Patent and Trademark Office.

The major issues of this patent was that it ignored centuries of documented Ayurvedic usage, prompting the Indian government (CSIR) to challenge it in 1997, proving prior art of such properties in India and that resulted in the revocation of the earlier patent.[44]

Basmati Rice

Basmati rice is a distinctive variety of rice from India and Pakistan. It has been consumed for centuries by people, but the problem began when in 1997, a US based company called RiceTec Inc. obtained a patent on Basmati ricelines.

The patent wanted to monopolize the term Basmati. This was harming the potential farmers of India and Pakistan. After a formal re-examination challenge by India (CSIR) in 2000, RiceTec withdrew 15 claims in 2001, severely restricting the patent and preventing monopolization of the generic term Basmati.[45]

Lessons from These Cases

The major lessons learned from the above cases are alarming. Biopiracy is one of the major concerns despite number of legal victories. Number of issues are there because the patent office failed to conduct a proper due diligence like making necessary searches in TKDL. Also, it is observed that the international patent law favours the corporations over in indigenous community and hence it is important for global regulations to protect AYUSH.

Role of WIPO and CBD in Protecting Traditional Medicinal Knowledge

World Intellectual Property Organization (WIPO) Initiatives

WIPO functions as a UN agency which has several mechanisms for protecting traditional knowledge.[46] The Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, Working towards an international legal instrument for TK protection. The Traditional Knowledge Division of WIPO delivers essential guidance to nations about incorporating TK protection measures into their IP systems.The Database of Genetic Resources and Traditional Knowledge supports patent offices to stop unauthorized use of traditional knowledge.

Convention on Biological Diversity (CBD) and the Nagoya Protocol

The Convention on Biological Diversity (CBD) together with its accompanying Nagoya Protocol on Access and Benefit Sharing (ABS) from 2010 work to distribute rightful financial rewards to indigenous populations when their traditional knowledge secures commercial profits.[47]

Key CBD & Nagoya Provisions for AYUSH

(i) National governments maintain full authority to regulate biological resource transfers because they serve as the custodians of their genetic resources.

(ii) Through the ABS mechanism organizations can obtain a fair share of revenue in situations where traditional plant knowledge leads to commercial use.

(iii) On top of PIC the requirement states that industry and research organizations have to request permission from resource owners before using biological resources based on traditional knowledge.

Challenges in Implementation

The implementation of international mechanisms to protect traditional knowledge faces several significant

hurdles. First, many developed countries oppose binding legal undertakings, which allows them to maintain weak enforcement measures. Additionally, India faces considerable difficulties in the implementation of benefit-sharing agreements, primarily because it struggles to ensure and enforce compliance from foreign corporations operating outside its borders. Finally, the parameters designed to protect AYUSH are subjected to diverse regulatory mechanisms across different international jurisdictions, which inevitably results in sporadic inconsistencies every time these protections are applied globally.[48]

Limitations of International Mechanisms in Safeguarding AYUSH

Western-Centric Patent System

The modern biotechnological innovations are given an upper hand in global IP systems in comparison to the community driven nature of AYUSH knowledge. Corporations are prioritised in patent laws of US, EU and other regions. Community based knowledge is often disregarded or claimed patent by other countries through unjust means.[49]

Difficulty in Proving Ownership

It is challenging to decide who should benefit from ABS agreements because AYUSH knowledge is collectively owned, furthermore, since any traditional formulations are not codified, it causes disagreements over who should own them.

Enforcement Challenges

Even when patents are revoked, legal battles are expensive and time-consuming. Countries like the US do not fully recognize ABS obligations under the Nagoya Protocol, allowing continued misappropriation.

Lack of a Global Traditional Knowledge Treaty

Following over two decades of negotiations by WIPO's IGC, the landmark WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge was adopted on May 24, 2024, establishing a mandatory disclosure requirement in patent applications. Countries like India must now lead efforts for its widespread ratification and domestic implementation to safeguard AYUSH.

Challenges in Protecting AYUSH as Intellectual Property

There are centuries of rich traditions and cultural heritage in AYUSH medical system however, the current frameworks do not provide sufficient protection. There are major problems like economic exploitation, misuse, and drawbacks in legal protection that is leading to danger to the importance of AYUSH in healthcare. The structure is emphasising on individual ownership and patenting, and majorly influenced by the legal concepts of western states. Such structures are dominating, making it incompatible with the collaborative and community based AYUSH practises.[29]

There are several drawbacks which lead to difficulties in defending AYUSH within the current framework of intellectual property rights. Thus, there is exploitation of traditional knowledge leading to fundamental tensions in AYUSH healthcare.[50]

Inadequacy of Existing Legal Frameworks

Lack of a Comprehensive National and International Legal Framework

The current legal mechanisms for protecting AYUSH-related traditional knowledge are fragmented and insufficient. Existing laws, such as the Indian Patent Act (1970), the Biological Diversity Act (2002), and the Traditional Knowledge Digital Library (TKDL), provide some safeguards, but they are not fully integrated with international IP frameworks.[51]

Patents: The Indian Patent Act excludes traditional knowledge from patentability, but foreign patent offices often grant patents for slight modifications of AYUSH formulations, leading to biopiracy. Geographical Indications (GIs): While some AYUSH-based products can be protected under GI laws, the protection is limited to specific regions and does not extend to knowledge systems. Copyright and Trademarks: Copyright protects literary and artistic works, not medicinal formulations, while trademarks protect brand names, not the underlying knowledge.

Implementation of the Global Traditional Knowledge Treaty

The traditional medicine knowledge is not protected under any international treaty. Though proposed framework exists(like WIPO and CBD), but such frameworks are non-binding. It is important to protect the traditional knowledge, but the developed nations oppose such practice arguing that it would restrict scientific research and innovation. The TRIPS does not provide for any explicit protection to community owned medical knowledge and that makes it easier for the

pharmaceutical companies to commercialise AYUSH knowledge for their profit making.[52]

Inconsistent Implementation of Benefit-Sharing Mechanisms

In India, Access and benefit sharing is mandated under India's Biological Diversity Act, 2002 to ensure that the community benefits are shared when the traditional knowledge is commercialised. However, due to the legal loopholes, the companies often bypass the ABS requirements and exploit the traditional knowledge. It is rare to observe that the indigenous practitioner receive fair compensation as there is lack of strict enforcement mechanisms. Also, the foreign companies use patent to monopolise medicinal plants and formulations, and that is very difficult to challenge for the AYUSH practitioners.[53]

Ethical Concerns and Community Rights

Who Owns Traditional Knowledge?

AYUSH is a collective knowledge system of India, which has developed through centuries, and it is not an individual invention. The modern IP laws have given an upper hand to individual ownership and that has created conflicts and issues on understanding who has the right to commercialise AYUSH knowledge. While the pharmaceutical companies claim patent on AYUSH based healthcare stating that they have refined and improved traditional formulations, on the other hand, the indigenous community and traditional healers are often disregarded and left out of the decision-making process, despite being the original owner of the knowledge.[54]

Exploitation of Indigenous Healers and Practitioners

There is dependence on AYUSH for healthcare by many tribal and rural communities. However, due to the commercialisation of AYUSH, there has been a huge loss of livelihood for the traditional practitioners. The medicinal plants are restricted from their access as they have now become prioritised and patented. Such practices also disrespect the cultural heritage as the traditional healing methods are commercialised and used in favour of profit making without giving proper credit or monetary benefit to the original owners.

Bioprospecting* v *Biopiracy

The ethical and legal exploration of traditional medicinal plants for scientific research inclusive of fair benefit sharing is called as bioprospecting. On the other hand, biopiracy involves theunauthorised and unethical appropriationof traditional knowledge by the corporate and researchers. Most of the companies involved in pharmaceutical products are engaged in biopiracy and hence leading to legal and ethical violations.

Commercial Exploitation and Misappropriation of Traditional Knowledge

Unfair Patent Practices and Biopiracy

Multinational pharmaceutical companies frequently file patents on traditional AYUSH remedies after making minor modifications, a practice known as biopiracy. Take example of the Neem Case wherein the European Patent Office (EPO) granted a patent for neem-based fungicidal products to W.R. Grace, despite neem being used in Ayurveda for centuries. India had to fight a long legal battle to revoke the patent. Another instance of the Turmeric Case where the USPTO granted a patent for turmeric's wound-healing properties, which had long been known in Indian medicine. The patent was revoked only after India provided historical evidence of turmeric's use.[55]

Pharmaceutical Corporations and Market Domination

Large pharmaceutical firms commercialize AYUSH products while excluding traditional practitioners from financial benefits. Companies often standardize and modify Ayurvedic formulations, claiming that their products are "improved" versions of traditional remedies. Traditional medicinal knowledge is often repackaged as "alternative medicine" in Western markets, diluting its original significance.

Threats to Sustainability and Biodiversity

Overharvesting of medicinal plants due to high commercial demand is endangering biodiversity. Monopolization of genetic resources by corporations makes it harder for traditional practitioners to access key ingredients.

Thus, AYUSH is at risk of both economic and ecological exploitation unless stronger protections are enforced.

Conflict between AYUSH's Holistic Approach and Western Patent Models

AYUSH Focuses on Holistic Healing, Not Just Individual Components

The Western patent system is based on isolating active ingredients from plants and proving their efficacy through controlled trials. AYUSH, however, follows a holistic approach, where treatments involve multiple herbs, lifestyle changes, and spiritual

practices.Patents fail to recognize this holistic nature, making it difficult to protect complex AYUSH formulations under existing IP laws.[56]

AYUSH v *Evidence-Based Medicine (EBM)*

Western medicine demands rigorous clinical trials before approving treatments.Many Ayurvedic, Unani, and Siddha formulations have been used for centuries but lack double-blind clinical studies, making patent approvals difficult.The challenge is to integrate traditional healing wisdom into scientific frameworks while maintaining its authenticity.[57]

Cultural Appropriation v *Global Acceptance*

Yoga is a prime example – While India promotes yoga as part of its cultural heritage, Western corporations have commercialized and trademarked yoga-related terms, profiting from an Indian tradition.Similarly, many Ayurvedic concepts are repackaged under different names, reducing their Indian identity.[58]

Proposed Models for Strengthening IP Protection of AYUSH

AYUSH is an integration of range of practices and forms of medicines, which are based in India. The system has a deep-rooted history and is a product of Indian culture. However, the existing legal national and international frameworks of IP protection are not strictly protecting such systems leading to wrongful appropriations, biopiracy, and unethical, commercialisation.

Though legal structures like the Traditional Knowledge Digital Library and Biological Diversity Act of 2002 do provide some form of protection, they rest on weak assumptions and fail to fully meet the expectations of protecting AYUSH. In this regard, this section will discuss four models aimed at strengthening the IP protection of AYUSH in India.

1. Sui Generis Systems for Traditional Knowledge Protection
2. Expanding the Scope of TKDL
3. Community Ownership Models and Benefit Sharing Frameworks
4. A National Policy on AYUSH and IP

These models are designed to protect the interests of indigenous people, traditional medical practitioners, and AYUSH specialists by blending modern IP regulations with traditional knowledge systems.

Sui Generis Systems for Traditional Knowledge Protection

What is a Sui Generis System?

A sui generis system is a type of law, one that is "of its own kind," which provides protection to traditional knowledge (TK) through its own unique and customized legal system. A sui generis system is more akin to a community based and traditional approach, rather than individualistic like patents, copyrights, or trademarks.

Why is a Sui Generis System Needed for AYUSH?

AYUSH practices do not constitute an invention, and are instead traditional, communal, and passed down orally, thus exclusionary patents cannot be applied.User protective laws like The Indian Patent Act of 1970, alongside the TRIPS Agreement, cannot sufficiently safeguard AYUSH practices as they overly stress novelty and singular ownership, rather than communal knowledge that is centuries old.Biopiracyinstances such as the misappropriation of neem, turmeric, and basmati rice patents illustrate the clear necessity there is for more tailored legal protection against such indiscriminate exploitation.

Features of a Proposed Sui Generis System

An exclusive form of IP right that provides traditional knowledge owners a privilege to exploit medicinal practises and AYUSH formulations. Having a mandatory disclosure of sources by the patent applicant and making sure that the sources of biological materials and traditional wisdom is contributed in their inventions are rightly disclosed. The indigenous communities and the AYUSH users are given a fair and equitable benefit sharing and guarantee them right payment. Setting up of national and local AYUSH knowledge registers to avoid any form of indiscriminative patent application and providing protection to indigenous medicinal knowledge.

A sui generis framework would protect unregulated privatization of AYUSH while guaranteeing that knowledge remains safe.

Expanding the Scope of the Traditional Knowledge Digital Library (TKDL)

The Role of TKDL in AYUSH Protection

It is a database for over 4.5 lakh formulations from different sources of traditional Indian knowledge like Ayurveda, Unani, Siddha, Yoga, etc. It is then translated into multiple languages to protect from misuse. The database has a direct access for the international patent offices so that it can prevent any

kind of unauthorised patent application. The database is evidence based and hence any kind of illegitimate claims can be challenged.

Limitations of the Current TKDL System

Even though there are number of provisions in TKDL to avoid misuse, there is still a lot of tension because of limited accessibility to Indian researchers, companies and practitioners due to their strict governmental control. There is more focus on defensive protection rather than having a proactive commercialisation and benefit sharing. Many valuable indigenous healing methods are neither covered nor protected.

Proposed Enhancements to TKDL

Since TKDL has a greater responsibility of protecting AYUSH, it is important to have effective inclusion of folk and tribal knowledge. An expansion to the database to include regional and tribal medicinal practises should be included. It is important to have an open access for Indian researchers and AYUSH practitioners as it would allow controlled access for commercial and scientific purposes and also at the same time, avoid biopiracy. TKDL can be integrated with international patent offices, making it a reference database for WIPO and other patent offices worldwide. AI driven tools can be made to monitor global patent filing and also in detecting potential misappropriation of AYUSH knowledge. Such practises can help India in protecting and promoting ethical and sustainable innovations.[59]

Community Ownership Models and Benefit-Sharing Frameworks

Why Community Ownership is Important

AYUSH knowledge is preserved and practiced by communities for centuries. However, most IP protection systems accommodate individual ownership and exclude the communities that are actually the custodians of this knowledge.

Proposed Community-Based Protection Models

(i) Traditional Knowledge Commons: Legal structure which acknowledges AYUSH as community property and allows some access with benefit sharing.
(ii) Collective Trademarks and Geographical Indications (GIs): Enabling tribal and indigenous people to secure GI and collective trademark for AYUSH medicines and products.
(iii) Traditional Healers' Societies: Licenses organized for practitioners of AYUSH in the form of cooperatives who can market their knowledge collectively.
(iv) Agreements for mandatory benefit sharing: Companies and researchers who set contracts with AYUSH practitioners are obliged to divide the income equitably.

Need for a National Policy on AYUSH and IP

Why there is a Need for a National Policy

India doesn't have a national policy on AYUSH and intellectual property. There is need for a policy to ensure ethical commercialization of AYUSH knowledge; to fortify legal structures for the protection of TK; to foster equitable and sustainable benefit-sharing mechanisms; to stop foreign appropriation and patent monopolies on Indian medicinal knowledge.

Main Components of the Proposed Policy

(i) Interrelationship of AYUSH and IP Laws: Proposing recognition of AYUSH knowledge as a form of intellectual property.
(ii) International Lobbying: Advocating for the recognition of AYUSH TK at WIPO, CBD, and WTO.
(iii) Government Sponsored AYUSH Innovation Grants: Funding initiatives from startups and research institutions in India to develop AYUSH healthcare solutions.
(iv) Mandatory Ethical Standards for Research and Commercialization: Pharmaceutical and biotechnology companies that deal with AYUSH knowledge are obliged to conduct ethical research.

A national AYUSH-IP policy will ensure that India's traditional and indigenous medical heritage structures will remain under Indian jurisdiction while ensuring their ethical development and innovation.

Conclusion

Preservation and safeguarding of AYUSH system's TK is one of the most important issues concerning modern-day intellectual property theorization and practice. India and other nations bearing rich medical heritage are indeed in need of stronger frameworks to prevent the looming danger of biopiracy, misappropriation, and insufficient legal protections. Problems pertaining to AYUSH include lack of an integrated and holistic IP system, reliance and interface between traditional knowledge systems and contemporary patenting faculties, and the absence

of benefit-sharing frameworks to ensure the protection and economic return to indigenous people. These strategies pose the need for holistic law and policy actions, institutional building, as well as global lobbying.

A specific legal system ought to be created in order to enhance the protection of Intellectual Property for AYUSH, so that Traditional Knowledge can be protected and recognized in the way other legal systems protect it, particularly in the absence of a standard law on patent. Modern pharmaceutical patents focus on aspects such as novelty and industrial applicability, which is contrary to what AYUSH formulations are based on because they are built on centuries old community practices. Hence, there is an urgent need to establish Traditional Knowledge Registries that enable indigenous communities to claim ownership rights over their medicinal knowledge. These registries should be granted Legal recognition and placed at the disposal of the public for the purpose of preempting the issuance of erroneous patent rights. This, along with the introduction of compulsory benefit-sharing agreements, would guarantee that businesses benefiting from AYUSH traditional knowledge would adequately reward indigenous people who preserved such knowledge for generations.

An important step in achieving these objectives has been to scale up and reinforce the Traditional Knowledge Digital Library (TKDL). While TKDL has successfully staved off the wrongful patenting of Indian traditional knowledge in several instances, there are still unmapped areas of ethnomedicine at the regional and tribal levels that need to be included. In addition, Indian researchers and AYUSH-based industries need to be propped up to foster innovation and development in the country by allowing them controlled access to the TKDL. With the incorporation of AI and Blockchain technologies, TKDL can strengthen its monitoring systems so that traditional knowledge is not patented globally without being credited to the original sources.

The use of Geographical Indications (GIs) and collective trademarks can further aid in the safeguarding of AYUSH knowledge. Granting GI protection to regionally specific AYUSH products like Kottakkal Ayurveda of Kerala or Siddha medicine of Tamil Nadu will avert their indiscriminate commercialization by foreign businesses as other non-regional businesses will not be able to sell these products without the consent of the producers. It is important to enable cooperative trademarks for AYUSH practitioners as that would lead to collectively having a control over the traditional knowledge which would lead to also receiving the right kind of monetary compensation. India should also work towards strengthening the international protection of traditional medical knowledge by engaging with organisations like the WIPO, WTO and CBD. It would be an improvement to amend the TRIPS Agreement so that patent applicants are required to disclose the source of traditional knowledge and benefit the source community. India should also shift the focus towards forming a treaty regarding the uniform protection of traditional medicine, in consonance with Nagoya Protocol, which enforces the member countries to take binding action.

A new set of legal tools and institutions capturing these changes needs to be put in place through a national policy on AYUSH and its relationship with intellectual property. This policy must design parameters to govern unethical commercialization along with providing incentives for research and strict controls against the misuse of traditional knowledge. It would strengthen the sector to also establish government sponsored AYUSH Innovation Funds to finance research and development efforts from other institutions and small firms working on solutions to healthcare problems using AYUSH. Also, ethical boundaries regarding cooperation between commercial pharmaceutical companies and AYUSH modalities must be defined to avoid situations of unethical sponsorship.

More attention should be paid towards forming AYUSH commercialization models that gain revenue while also protecting the interests of intellectual property.

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