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TRADITIONAL MEDICINAL KNOWLEDGE AND INTELLECTUAL PROPERTY RIGHTS

AUTHORED BY - SANCHITA.S & SRINITHI. V

INTRODUCTION:

Traditional knowledge and intellectual property rights (IPR) are two concepts that are not often associated with each other. Traditional knowledge is owned collectively by a community and can take many forms such as songs, stories, proverbs, folklore, beliefs, rituals, local languages, community laws, and practical fields such as agriculture, horticulture, forestry, fisheries, health and environmental management. For a long time, traditional knowledge went unprotected. However, it is a crucial element in achieving sustainable development. Attempts to exploit traditional expertise for industrial or commercial advantages can result in its rightful holders being misappropriated of the same. Every year on April 26, we observe World Intellectual Property Day to encourage conversation about how intellectual property (IP) can foster creativity and innovation. The Universal Declaration of Human Rights as per Article 27 states that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author". Therefore, it is important to develop ways and means of preserving and maintaining traditional knowledge so that sustainable development is consistent with traditional knowledge interests.

The protection of Traditional Medicine TM under Intellectual Property Rights (IPRs) raises two major questions: to what degree can TMK be protected under the current intellectual property rights system, and to what extent can Traditional Medicine Knowledge be protected under the current IPR system. However, there is no separate law for traditional medicinal knowledge, which puts it at risk. Codified laws are necessary to protect Traditional Medicinal Knowledge from being exploited by third parties. This paper highlights the need for an effective and strong law for the protection of traditional medicinal knowledge, similar to any other Intellectual Property Rights.

WHAT IS TRADITIONAL KNOWLEDGE AND ITS WORKING MACHANISM

Traditional knowledge is a type of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. TK encompasses the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with TK. It refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations. Traditional knowledge can be found in a wide variety of contexts, including agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge. Although there are no universally accepted definition of Traditional knowledge, at the International stage, it has been generally understood to be a cumulative body of knowledge, know-how, practices and representations are maintained and developed by the people.

Article 8(j) of the Convention on Biological Diversity defines traditional knowledge as the awareness, inventions, and traditions of local and indigenous cultures worldwide. The most important element of traditional knowledge is that it has an ancient origin and is mostly oral.

Traditional knowledge in IPR is usually protected through two methods - positive protection and defensive mechanism. Positive protection involves providing traditional knowledge holders with the rights to take necessary action and seek remedies against the misuse of the knowledge base. It involves the enactment of specific rules and regulations and laws, as well as access to benefit-sharing provisions, royalty payments, etc. In India, the Traditional Knowledge Digital Library (TKDL) was launched to record and circulate all traditional knowledge through an e-library. TKDL provides information on scientific and traditional knowledge.

TRADITIONAL MEDICINAL KNOWLEDGE

Traditional Medicine has a long history that can be traced back to the early days of human civilization when humans were hunter-gatherers. The origin of Traditional Medicine may have been from the search of early humans for remedies for their various illnesses. Through a method of trial and error, and dictated by the knowledge preserved in their genes, they might have developed various medicines, mostly of herbal origin. Archaeological evidence suggests that the

use of plants for medicinal purposes dates back to more than 60,000 years, and written records are traced back to about 5000 years. As medicinal knowledge expanded over time, some of it got streamlined into various systems. India has Ayurveda, Yoga, Siddha, Unani, Sowa Rigpa, and other countries have their systems, including Traditional Chinese Medicine. Chiropractic and Homeopathy, though are not exactly Traditional Medicine, they are considered complementary medicines to traditional Medicine.

According to the World Health Organization (WHO), “traditional medicine” is a comprehensive term that encompasses the sum total of knowledge, skill, and Practices that are based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness. It includes diverse health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral-based medicines, spiritual therapies, manual techniques, and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose, or to prevent illness. Traditional Medical Knowledge (TMK) is an important aspect of most local cultures identities. However, it is at risk due to a lack of paperwork and proper legislation. Third parties are using and patenting this information without the permission of the original holders, who often receive little or no financial gain. The documentation and digitization of Traditional Knowledge-related literature is necessary to preserve and protect it from third parties. TKDL is an effective means of achieving this goal. Traditional medicine is usually based on medicinal herbs and centuries-old indigenous knowledge, but there is no official documentation for Traditional Medicine Knowledge. The majority of Traditional Medicine Knowledge was passed down orally from generation to generation. Traditional remedies are often based on medicinal plants that are local to the countries where the system has been in use for centuries.

RESEARCH PROBLEM:

The Traditional Medicinal Knowledge has been preserved due to the strong cultural values and the practices that emphasizes on the traditional healong methods and practices. For example, in many African societies, traditional healers are highly respected members of the community, and their knowledge is deeply ingrained in cultural traditions. In these contexts, traditional medicinal knowledge is often transmitted through family lineages or apprenticeships between master healers and their students.

However, in other cultural contexts, traditional medicinal knowledge has declined due to various factors such as colonization, modernization, and globalization. Colonization often led to the suppression of traditional healing practices and the imposition of Western medicine as the dominant form of healthcare. Modernization has also contributed to the decline of traditional medicinal knowledge as many indigenous communities have migrated to urban areas in search of employment and modern amenities.

In recent years, there has been growing recognition of the importance of traditional medicinal knowledge and its potential contributions to modern healthcare systems. However, there are still significant challenges and opportunities for integrating traditional medicinal practices into modern healthcare systems while respecting cultural values and intellectual property rights. Some of these challenges include:

1. Intellectual Property Rights: Many indigenous communities consider traditional medicinal knowledge to be a part of their cultural heritage and believe that it should not be subjected to intellectual property laws that favor commercial interests. This has led to debates over how to balance the need for protecting traditional medicinal knowledge with the need for promoting innovation and access to medicine.
2. Regulatory frameworks: There is a lack of regulatory frameworks that can ensure the safe and effective use of traditional medicines while respecting cultural values and intellectual property rights. This has led to concerns over the quality, safety, and efficacy of traditional medicines that are sold in markets or exported to other countries.
3. Cultural Sensitivity: There is a need for greater cultural sensitivity in integrating traditional medicinal practices into modern healthcare systems. This involves recognizing the unique cultural contexts in which traditional medicinal knowledge is generated and used, as well as respecting the role of traditional healers as key stakeholders in healthcare delivery systems.

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RESEARCH QUESTION:

1. What degree can TMK be protected under the current intellectual property rights system ?
2. How has traditional medicinal knowledge been passed down through generations and what factors have contributed to its preservation or decline in different cultural contexts.

RESEARCH METHODOLOGY:

In this research paper Emphirical , Hermeneutic and Evaluative research has been followed. This research is based on both the Primary and Secondary Data. The Primary ones being the Statutes , cases and books while the Secondary data includes the articles , blogs and journals , website used for the references in the formation of the paper. These referred to understand the Background of the paper and the research question.

INDIAN CONTEXT OF TRADITIONAL MEDICINAL KNOWLEDGE:

Folk customs in India are transmitted verbally from one generation to the next. The foundation of "folk" medicine is a century's worth of household-level achievements and failures, as well as customs, beliefs, and practises. These can be referred to as "people's health culture," home remedies, or folk cures because they are passed down orally. An individual may possess traditional medicine (TM). Despite disclosure of the photochemical goods or processes utilised, healers can utilise rituals as part of their traditional therapeutic practises, which frequently allows them to monopolise their expertise. The thousands of manuscripts that span all specialties of medicine include profound medical information that is part of the codified heritage. The Tibetan medicine , Ayurvedic, Siddha, and Unani are the codified scriptures that contain all the branches of traditional medicine.

Numerous formulas for Ayurvedic, Siddha, and Unani medicine are patented. They are mostly for procedures.

- a. A method for making anti-snake Ayurvedic venom.
- b. An Ayurvedic concoction to fuse broken bones.
- c. Ayurvedic herbal mixture used to cure psoriasis.
- d. A method for making the unique Unani mixture Jigirina, which is used to cure jaundice and viral hepatitis.
- e. A herbal remedy for regulating blood sugar levels and a method for making it.
- f. A herbal remedy for bronchial asthma and the method for making it.
- g. A synergistic herbal antiulcer formulation.
- h. A herbal remedy designed to address diabetes.
- i. Ayurvedic antiretroviral mixture for acquired immunodeficiency syndrome treatment.
- j. An oral Ayurvedic formula for the management of hypertension and heart conditions.

TURMERIC PATENT CASE:

Turmeric is a tropical herb that is grown in East India and is widely used in India for various purposes such as medicine, food ingredient, and dye. It is used as a blood purifier, in treating the common cold, and as an anti-parasitic for many skin infections. It is also an essential ingredient in cooking many Indian dishes. The patent for the use of turmeric powder and its administration, both oral and topical, for wound healing was granted to Suman K. Das and Hari Har P. Cohly, who later assigned the patent to the University of Mississippi.

The Indian Council for Scientific and Industrial Research (CSIR) had objected to the patent granted. The USPTO revoked the patent, stating that the claims made in the patent were obvious and anticipated, and agreeing that the use of turmeric was an old art of healing wounds. Therefore, the Traditional Knowledge that belonged to India was safeguarded in the Turmeric case. In 2018, the US Patent and Trademark Office rejected the patent, recognizing that turmeric is part of India's cultural heritage and should not be subjected to intellectual property laws that favor commercial interests without proper consideration of traditional medicinal knowledge.

THE NEEM CASE:

W.R. Grace and the United States Department of Agriculture submitted the Neem patent application to the European Patent Office. The patent describes a technique for utilising a formulation of neem oil to control fungus on plants. India has lodged a lawsuit to prevent the patent from being granted. The protest was filed by Magda Aelvoet, a former green Member of the European Parliament (MEP), the International Federation of Organic Agriculture Movements (IFOAM), and the Research Foundation for Science, Technology, and Ecology (RFSTE), located in New Delhi. India's beloved neem tree is home to several powerful substances, most notably azadirachtin, which is present in the seeds of the plant. The Neem tree's bark, leaves, flowers, and seeds are used to cure a wide range of illnesses, including ulcers, diabetes, skin conditions, and leprosy. Since the beginning of time, neem twigs have been used as antiseptic toothbrushes. The opponents presented documentation from old Indian Ayurvedic books that explained how hydrophobic neem seed extracts were used for millennia in India to treat human dermatological conditions and shield crops from fungal infections. The patent was revoked by the European Patent Office due to its lack of innovation, inventive step, and potential formation of relevant previous art. Recently, a number of US patents for neem-based emulsions and solutions were filed. In 2003, the US Court of Appeals for the Federal Circuit overturned the patent, recognizing that neem is part of India's cultural heritage and should not be subjected to intellectual property laws that favor commercial interests.

BASMATHI CASE:

The Basmati patent case is a well-known ruling about conventional medical wisdom. A US business named Pioneer Hi-Bred International filed for a patent on a process for making Basmati rice in the late 1990s. Grown traditionally in India and Pakistan, basmati rice has long been a significant component of both countries' cultural legacies.

The patent was contested by the Indian government and a number of non-governmental organisations (NGOs), who said that since basmati rice is a traditional variety, it shouldn't be protected by intellectual property laws that prioritise business interests over traditional medical expertise. The World Trade Organisation (WTO) heard the case all the way through and rendered a decision in 2003 that favoured Pakistan and India.

The WTO decision was a significant victory for indigenous communities and their traditional

medicinal knowledge, as it recognized the importance of preserving cultural heritage and traditional practices. However, there are still challenges related to intellectual property rights and traditional medicinal knowledge, as outlined in my previous response. The Basmati patent case highlights the need for greater cultural sensitivity and respect for traditional medicinal knowledge in intellectual property law, as well as the importance of recognizing the unique cultural contexts in which traditional medicinal knowledge is generated and used.

INTERNATIONAL POLICIES ON TRADITIONAL MEDICINE:

A number of worldwide laws and initiatives have been launched in addition to these well-known rulings with the goal of addressing the issues surrounding traditional medical knowledge and intellectual property rights. Here are few instances:

I. Beijing Convention:

In November 2008, a proclamation endorsing traditional medicine was adopted by government representatives from WHO Member States in Beijing. Representatives from WHO Member States convened for the first time specifically to debate traditional medicine and craft an advocacy document at the WHO Congress on Traditional Medicine. They acknowledged traditional medicine's contribution to bettering public health in the Beijing Declaration and backed its appropriate integration into national health systems. The proclamation urges national policy on traditional medicine to be developed or enhanced. It also encourages better clinical investigation, teaching, and research in conventional medicine, as well as better health care provider-to-healthcare provider communication.

Key Points:

1. It is important to respect, maintain, promote, and disseminate information about traditional medicine, therapies, and practises in a way that is appropriate for the circumstances in each nation.
2. As part of complete national health systems, governments have a duty to ensure the appropriate, safe, and effective use of traditional medicine. To this end, they should develop national rules, regulations, and standards.
3. We urge governments who have not yet done so to act, acknowledging the progress made by many in incorporating traditional medicine within their national health systems.

4. In accordance with the "Global strategy and plan of action on public health, innovation and intellectual property," which was established at the Sixty-first World Health Assembly in resolution WHA61.21 in 2008, traditional medicine should be further developed based on research and innovation.
5. The execution of the global strategy and action plan should involve cooperation from governments, international organisations, and other stakeholders.
6. Systems for the certification, licencing, or accrediting of practitioners of traditional medicine should be established by governments. Practitioners of traditional medicine should update their training in accordance with national standards.
7. Appropriate training programmes for health professionals, medical students, and relevant researchers should be established, and contact between conventional and traditional medicine providers should be increased.

II. UNITED NATIONS DECLARATION ON THE RIGHTS OF INDIGENOUS PEOPLE

1. Article 24:

Indigenous people are entitled to use their traditional medicines and to continue practising their traditional medicine, which includes protecting their essential medicinal plants, animals, and minerals. Indigenous people also have the right to use all social and health services without facing any prejudice.

Everyone, including Indigenous people, has an equal right to the best possible level of bodily and mental well-being. States must take the required actions in order to gradually realise this right in its entirety.

Article 31:

Native Americans have the right to preserve, manage, safeguard, and advance their traditional knowledge, cultural expressions, and cultural heritage. This includes the ways in which their sciences, technologies, and cultures are expressed, such as through the use of seeds, medicines, human and genetic resources, knowledge of the characteristics of plants and animals, oral traditions, literature, designs, sports, traditional games, and the visual and performing arts. In addition, they are entitled to the upkeep, management, defence, and development of their intellectual property, which includes traditional knowledge, cultural expressions, and cultural assets.

States shall implement adequate measures to acknowledge and safeguard the exercise of these rights in cooperation with indigenous peoples.

TRADITIONAL MEDICINE AND INTELLECTUAL

PROPERTY RIGHTS:

Indigenous and traditional peoples have made enormous contributions to the preservation of the world's biodiversity and associated traditional medical knowledge. New knowledge on natural oils, body enhancement and skin care products, cures for various ailments, and other health-related topics is constantly being discovered through everyday ethnobotanical and related surveys and study. As the globalised economy looks to traditional and indigenous societies for further "explorations" into the diseases of today, new and difficult issues are emerging.

Viewed as a fundamental human right, access to and sharing of the world's biological resources clash with the property rights of traditional or indigenous groups, who are considered the "inventor" of these resources.

Trade is the commodification of all available resources, including materials, conventional medical procedures, and ideas, and it typically occurs without any benefit to the nation or community of origin.

Because Intellectual Property Rights (IPRs): -recognise individual, not collective rights, require a specific act of "invention" , simplify ownership regimes , stimulate commercialization , recognise only market values , are subject to economic powers and manipulations , are expensive, complicated, and time-consuming and are subjected to manipulation. Hence the current IPR laws are insufficient and inadequate for the protection of medicinal knowledge. Nations with a wealth of innovations in traditional medicine, such as China or India, stand to gain from IPR applications, whereas non-innovators who use medicines may suffer consequences. Traditional medicine's inadequate documentation works against recently documented fields since it lowers their priority in the IPR hierarchy.

It is impossible to isolate the issues facing indigenous communities from the implications of IPRs pertaining to indigenous people. Numerous villages either entirely vanished or were incorporated into the idea of "modernization." A great deal of the customs and uses will soon be lost to history.

Traditional life is threatened by the introduction of money into production-consuming connections. The young people's desire to make more money faster drives them to the big cities, which breaks down the informational flow from the older to the younger: Traditional medical systems become discontinuous as a result of this lack of interest.

Throughout the history of colonisation and invasion, encounters between populations formed by various evolutionary processes have frequently resulted in devastating outcomes. In indigenous and traditional societies with great biodiversity, Western commercial companies, which are fiercely competitive, are acting like invasive invaders.

The drawbacks include the organisational and related shortcomings in emerging nations and their inability to compete in the global economy.

I. Biological Diversity Act, 2002:

India thought it acceptable to provide an outcome to the Convention on Biological Diversity (CBD), since it is a signatory to that agreement. India subsequently passed the Biological Diversity Act of 2002 in order to promote the preservation of biological diversity, the sustainable use of its components, and the equitable distribution of earnings from the exploitation of natural resources. The rule addresses the following essential problems:

- Right to use to natural assets.
- Gathering and consumption of natural assets.
- Dividing the profits occurring out of such entrance.
- Safeguarding from Bio Piracy.

The National Biodiversity Authority (NBA) under section 8, the State Biodiversity Board (SBB) under section 22 of the Act, and Biodiversity Management Committees (BMCs) are established at the local community level by the law. Without prior approval from the NBA, no one may file for any intellectual property rights in or out of India for any discovery based on research or knowledge on an Indian natural reserve. The act establishes a framework for property rights with a strong emphasis on limiting access to biological resources outside of India. Additionally, the law stipulates that the individuals in charge of creating, advancing, and utilising this technology for commercial purposes will split the profit structure.

II. The 1970 Patent Act:

The patent statute is relevant for the protection of technological solutions that are uniformly new, scientifically significant, and need a creative stage. For instance, things that are synthesised, generated from genetic structures, microorganisms, plants, animals, or organisms living in their environment may not be eligible for patent protection, and patents for genetic resources and technology may be withdrawn. Processes related to the use and exercise of those assets are eligible for patent protection, as are procedures that are well-known to indigenous communities and satisfy the same standards.

III. The 1957 Copyright Act:

The means of speech and expression are protected by copyright, not the ideas themselves. Section 14 of the Copyright Act, 1957 permits the copyright holder to do any of the specified measures. Copyright can be utilised to protect the creative expression of TK holders, particularly those who are artists from indigenous and indigenous groups, from unauthorised use and copying. Moral rights govern the connection between authors, artists, and creators and their works.

To protect traditional medicinal knowledge under intellectual property rights laws, several strategies can be adopted:

1. Documentation and preservation: Traditional medicinal knowledge needs to be documented and preserved to prevent its loss due to cultural erosion, globalization, and modernization. This documentation can be done through various methods such as oral history, written records, and audio-visual recordings. The documentation should also include information on the cultural contexts in which traditional medicinal knowledge is generated and used.
2. Intellectual Property Protection: Traditional medicinal knowledge can be protected under intellectual property laws such as patents, trademarks, and copyrights. However, these protections should be balanced with the need to respect cultural heritage and traditional practices. This can be done by recognizing the collective ownership of traditional medicinal knowledge by indigenous communities and by requiring prior informed consent before accessing their genetic resources or traditional knowledge.
3. Traditional knowledge databases: Traditional medicinal knowledge can be compiled into databases that are accessible to researchers and healthcare professionals around the world. These databases should include information on the ingredients, uses, and safety

profiles of traditional medicines, as well as information on the cultural contexts in which they are used. The databases should also be protected by intellectual property laws that recognize the cultural heritage and traditional practices associated with traditional medicinal knowledge.

4. **Collaboration and Dialogue**: There is a need for continued dialogue and collaboration between indigenous communities, healthcare professionals, policymakers, and researchers from various fields such as anthropology, law, medicine, and science. This dialogue should focus on finding ways to respect cultural heritage and traditional practices while promoting the safe and effective use of traditional medicines in modern healthcare systems. It should also involve indigenous communities in decision-making processes related to healthcare and development.
5. **Capacity Building**: Indigenous communities need to be empowered with the skills and resources necessary to manage their traditional medicinal knowledge in a sustainable manner. This can be done through capacity building programs that provide training in areas such as documentation, preservation, intellectual property protection, and commercialization of traditional medicines. These programs should also involve indigenous communities in decision-making processes related to healthcare and development.

Actions that Could and Should be taken:

1. It is important to fully develop and employ national and international IPR enforcement procedures that guarantee lawful access to traditional knowledge and genetic resources.
2. It is important to preserve and strengthen the political and legal latitude in the current international agreements and negotiations to create and execute defensive and proactive national sui generis (specially formed) systems to safeguard conventional medical knowledge.
genetic resources or traditional knowledge.
3. **Traditional knowledge databases**: Traditional medicinal knowledge can be compiled into databases that are accessible to researchers and healthcare professionals around the world. These databases should include information on the ingredients, uses, and safety profiles of traditional medicines, as well as information on the cultural contexts in which they are used. The databases should also be protected by intellectual property laws that recognize the cultural heritage and traditional practices associated with traditional medicinal

knowledge.

Conclusion:

The creation of intellectual property, as well as its valuation, usage, and protection, are becoming more and more significant in today's world. The properties of traditional and indigenous life are being destroyed by the rapidly changing modern world. Regretfully, these cultures, rich in biodiversity and values, are also among the poorest of all countries and communities. The people with the most natural wealth and indigenous wisdom also have the least access to cash, technology, infrastructure, and legal processes. The fundamental contradiction arises from the incompatibility of traditional health systems, which incorporate traditional knowledge and property protection systems, with the uniform, standardised commercial systems of developed capitalist nations.

An International Traditional Knowledge Resource Classification System will be used to integrate the Traditional Knowledge Digital Library with the International Patent System, which will significantly improve the situation going forward.

Not to mention, it is challenging to integrate a healer who performs this work for a purpose rather than financial gain into the marketplace. Even while money was first used as a means of commerce, it now has a worth of its own and obscures other values in life. In order to satisfy the expanding needs of the populace of this nation, business entities should gradually tap into the huge ocean of traditional knowledge (TK), while maintaining respect for the rights of the indigenous people and India's cultural legacy. Additionally, as the present rules support the advancement of community rights and create an atmosphere that is favourable to patents, it is important to proactively promote benefit sharing agreements in order to preserve the equilibrium between inventors and TK holders.

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- The Copyright Act, 1957

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- Neem Case
- Basmathi Case

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