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Patent Applications and Protection of Traditional Medicine under the Global Intellectual Property Law Framework

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Abstract: Traditional medicine is deeply rooted in different cultures and remains an important global medical resource. However, the intellectual property protection of traditional medicines faces significant challenges in the global legal framework. Issues such as biopiracy, lack of novelty, difficulties in attribution and inconsistent national implementation hinder the effective patenting of traditional medical knowledge (TMK). This paper examines current international IP regimes relevant to TMK, including the Patent Cooperation Treaty (PCT), the Convention on Biological Diversity (CBD), and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). By analyzing case studies from China, India and Peru, this study identifies gaps in the legal framework and proposes improvements such as specialized patent laws, electronic TMK files and equitable benefit-sharing mechanisms. Strengthening legal frameworks and harmonizing international policies can improve the protection of TMKs and ensure fair recognition and sustainable use for future generations.

Keywords: Traditional Medicine; Patent Protection; Biopiracy.

1. Introduction

Traditional medicine is a medical practice with a long history and cultural roots that has gained popularity around the world. For many people around the world who live in poverty and far from urban centers with advanced health systems, traditional medical knowledge (TMK) remains the primary source of healing. Not only is it important to many indigenous peoples and local communities, but in some countries in Asia and Africa, many people rely on traditional medicine, including for primary health care. In many developed countries, 70-80% of the population has been treated with alternative medicine such as acupuncture. Natural resources and associated traditional knowledge are the basis for the development of many modern medicines and vaccines [1].

However, such knowledge has long been recognized in various mainstream legal and social discourses as primitive, archaic, and lacking modern commercial value. Some types are highly developed and well documented, with a systematic body of knowledge, comprehensive methodologies, and a long history of experience. However, many less sophisticated TMK practices are largely derived from local experience and exist among less populated and sometimes remote minority groups, whose knowledge may not be documented and is often passed down from generation to generation by oral tradition. This negative categorization of TKM marginalizes TKM communities and holders and can lead to negative impacts on TKM, including misappropriation for exploitation and commercialization, as well as loss of value in the process of globalization and modernization [2].

As a result, traditional medical knowledge continues to face a number of problems in patenting today. Issues such as biopiracy, attribution, proof of disclosure, lack of novelty, etc., require countries to balance the legitimate interests of different stakeholders. While many international regulations provide much support for global intellectual property rights, they also face the challenge of inconsistent implementation of national laws. This paper examines the role of the existing international IP legal system in the patent protection of traditional medicines and the issues that need to be addressed by analyzing various international regulations and agreements, as well as the policy and practice cases of China, India, and Peru.

2. Status of International Intellectual Property Protection for Traditional Medicine

2.1. The Concept of Traditional Medicine

According to the World Health Organization (WHO), Traditional medicine is the sum of knowledge and experience used to maintain health and to prevent, diagnose, alleviate, or treat physical and mental illness. It exists in different cultures and consists of knowledge, skills and practices based on theories, beliefs and experience [1]. raditional medicine is a broad term that refers to both traditional systems of medicine, such as traditional Chinese medicine (TCM), Ayurvedic medicine, and Unani medicine, and indigenous medicine practiced according to tradition. Traditional medicines can be made from various ingredients, including herbs, medicinal plants, preparations, and finished herbal products.

Like other modern medicines, traditional medicines are covered by health policies and regulatory systems in many countries. This ensures that they meet standards of safety, quality and efficacy. However, there are still underdeveloped countries where traditional medicines are not regulated to ensure their safety. Depending on national laws and regulatory systems, traditional medicines may also be available in pharmacies or hospitals in the form of prescription medicines, over-the-counter medicines, health foods or functional foods [3].

2.2. Characteristics of Traditional Medicinal Knowledge

2.2.1. Collective Creation

"Traditional" implies that knowledge is created in a way that reflects the traditions of the community, that it is often passed down from generation to generation, and that it is created and preserved in a collective manner. This is different from individual patents or copyrights in modern intellectual property systems. Because knowledge in traditional medicine is created collectively over a long period of time, traditional knowledge is often considered to be the collective heritage of a particular indigenous population or local community, rather than that of an individual or small group of individuals. Although some individuals, such as the Bolivian shaman or the South African witchdoctor sangoma, may be able to innovate on their own, their innovations can be characterized as "traditional" because they are based on the collective heritage of the community and are seen as knowledge held by the community as a whole[1].

2.2.2. Personalized Treatment

The practice of traditional medicine, especially across health care systems such as TCM, shares many of the same core values. The practice of customizing and adapting treatment plans based on an individual's unique constitution, pathology, lifestyle, environmental factors, etc. is common. This approach is similar to the concept of "personalized medicine" in modern medicine, which emphasizes differentiated treatment for each patient's unique situation rather than a one-size-fits-all standard treatment approach. These practices are often characterized by the use of highly individualized treatments that maximize the body's innate ability to heal, encourage patients to be active participants in the resolution of their illnesses, and place a high priority on disease prevention.

2.2.3. Regional Differences

Traditional medicine is very diverse and can vary greatly from region to region. Climate, soil, water, plant, and animal resources vary greatly from region to region, which directly influences the selection and use of herbs in local traditional medicine. For example, colder regions may focus more on warming medicines, while tropical regions tend to use heat-cleansing and detoxifying medicines [4]. Traditional medicine is also strongly influenced by local cultural and religious beliefs. For example, the yin-yang and five-element theories of Chinese medicine, the santosha theory of Indian Ayurveda, and the spiritual healing of African traditional medicine reflect their respective cultural systems' understanding of health and disease. In addition, different jurisdictions still have different interpretations and variations of TMK IP protection. This is because each country has its own unique cultural traditions, social characteristics, historical and geographical features, identity and value systems.

3. International Intellectual Property Law Relating to Patent Protection for Traditional Medicine

3.1. Patent Cooperation Treaty (PCT) International Application

The PCT is an international treaty for cooperation in the field of patents [5]. Its purpose is to solve the problem of reducing the duplication of efforts between the applicant and the various patent office's when applying for patents for the same invention or creation in more than one country or region. This is particularly useful for applicants who wish to protect their TK in multiple countries.

In addition, the PCT system provides a mechanism to extend the time for examination of patent applications, giving applicants more time to evaluate market and patent strategy before deciding in which countries to seek protection. This allows better planning and preparation for applicants with knowledge of traditional medicines. In addition, while the PCT itself does not directly regulate benefit-sharing mechanisms, it does assist countries in implementing their own benefit-sharing laws. For example, when applying for a patent using traditional medicinal knowledge, an applicant may be required to share benefits with the holder of the knowledge under the law of the country concerned. However, there are still some problems, such as the complexity and cost of the PCT application process, which may make it difficult for many communities or individuals relying on traditional medicines to afford the costs of application and legal advice. In addition, the risk of public disclosure and the requirement for patentability are also deterrents to traditional medicine applications, which I will explore further below.

3.2. Convention on Biological Diversity

The Convention on Biological Diversity (CBD)[6] aims to promote the conservation of biological diversity, the sustainable use of natural resources, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, while ensuring that countries have access to and control over their own genetic resources.

Article 8(j) of the Convention provides for the respect, protection and conservation of traditional knowledge, innovations and practices of indigenous and local communities, and, with the consent and participation of the holders, to promote their wider use and ensure the equitable sharing of the benefits arising therefrom.[6] The law not only explicitly recognizes the contribution of indigenous and local communities to biodiversity conservation and the rights of indigenous peoples to the knowledge they possess. The CBD also calls for the fair and equitable sharing of the benefits arising out of the utilization of knowledge related to genetic resources among countries on mutually agreed terms.

While the CBD recognizes the sovereignty of states over biological resources and the right of communities to hold traditional knowledge, it does not impose standards. Instead, it allows countries to develop their own legislation in this regard. Unfortunately, however, only a few countries today seem to recognize the importance of traditional medical knowledge and have enacted relevant legislation. The majority of countries have not enacted legislation to regulate access to their traditional medicines and genetic resources.

3.3. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement regulates the nature and obligations of pharmaceutical patents and test data protection. Article 27 of the TRIPS Agreement provides that a patent must be "grantable for any invention, whether a product or a method of making, in all fields of technology".[7] The reference to "all fields of technology" means that patents may be granted for pharmaceutical products, such as new compounds with pharmaceutical activity, as well as for manufacturing

processes, such as processes for producing pharmaceutical products. It also provides that patents are protected for a period of 20 years from the date of filing. Article 7 of the TRIPS Agreement describes the objectives of the protection and enforcement of intellectual property rights, mainly in terms of the balance between rights and obligations.[7] The objective is to promote technological innovation, transfer and diffusion, and to generate mutual benefits for both creators and users of knowledge, as well as social and economic welfare.[4]

However, when trying to apply the TRIPS standards for pharmaceuticals to traditional medicine, it quickly becomes clear that the existing provisions do not meet the needs and realities. For example, a major shortcoming of most forms of intellectual property rights is the lack of mechanisms to deal with collective intellectual property rights. the TRIPS provisions for patent protection require novelty, innovation and utility, criteria that are often inapplicable to traditional medicines. in short, the TRIPS agreement itself provides limited protection for traditional medicines. In short, the TRIPS Agreement itself provides limited protection for traditional medicines, and relies on country-specific laws and policies for more comprehensive protection.

4. Traditional Medicine Patent Applications

4.1. PCT Application Requirements

The Patent Cooperation Treaty (PCT) allows an invention to be protected simultaneously in all PCT contracting states by filing an international patent application. The application is filed by the applicant in the country of origin with the national patent office, with an appropriate regional patent office or with the International Bureau in Geneva.[8]

The PCT specifies in detail the formal requirements that all international applications must comply with, namely the five standards that all patent laws have[5]: (i) the patent application must be a patentable subject matter; (ii) the claimed subject matter must be new; (iii) it must be inventive or non-obvious; (iv) it must be suitable for industrial application or useful in accordance with Article 27 of the TRIPS Agreement; and (v) the invention must be adequately disclosed in accordance with Article 29 of the TRIPS Agreement[7]. The above requirements must be met simultaneously, and failure to meet any one of the conditions will result in the rejection of the patent application.

4.2. Challenges in the Patenting Process for Traditional Medicine

4.2.1. Unable to Identify the Applicant

To register a patent, one needs to specify the inventor, so identifying who the inventor of TK is may not always be easy. Usually, the TMK has been accumulated as part of its historical background within a certain community or ethnic group by collective creation and development. This type of traditional medical knowledge is not the work of just one person or a small number of people, but rather is the collective wisdom of an entire community that has been passed on through generations over a long history. In this regard, it becomes difficult to pinpoint any specific individual, organization, or company as the sole applicant of the patent. Modern patent laws would require clear identification of the inventor or applicant in order to legally grant them exclusive rights and benefits. Such a requirement, as far as collectively generated traditional medical knowledge is concerned, represents a contradiction of the truth.

4.2.2. Difficulty in Recognizing Novelty and Creativity

Holders of traditional medical knowledge may face significant challenges in meeting the requirements for obtaining a patent, particularly with respect to the novelty and inventiveness requirements. Because many traditional medicines have been used for generations, are widely practiced in local communities, and are documented in publicly available information, they may not be eligible for patent protection due to lack of novelty. For example, the Development of Chinese medicine Lianhua Qingwen , which plays an important therapeutic role in China, is based on a Chinese infectious disease (pestilence).[9] Its ingredients include honeysuckle, licorice root, apricot seeds and forsythia to treat coronavirus. It played a prominent role in both the SARS and MERS incidents. However, LHQW is difficult to meet international intellectual property registration standards and has not been granted any international patents or even considered an effective drug, mainly because it uses herbs that are publicly available and novelty cannot be adequately demonstrated.

The high standard of inventiveness is another significant barrier to patenting traditional medicines. Natural product medicines usually involve some form of modification or purification, and whether such compounds are novel and inventive compared to naturally occurring substances is often the key to patent examination.[4] Because herbal remedies often contain unprocessed natural products, it is difficult to demonstrate novelty and inventiveness in these therapies. It is also often a challenge to distinguish the prior art from the invention for which protection is sought in patent applications, and this distinction is a prerequisite for assessing inventiveness. As a result, the inventive step requirement for herbal remedies is often difficult to meet, especially when it comes to distinguishing the invention from the prior art.

4.2.3. Safety and Efficacy Cannot be Guaranteed

The use of traditional medicine poses unique public health challenges. According to WHO, "inappropriate use of traditional medicines or practices can have adverse or dangerous effects, and further research is needed to determine the efficacy and safety of many traditional medical practices".[8] However, traditional methods of herbal identification, such as morphology, microscopic examination, and chemical analysis, are often insufficient to accurately and reliably identify a large number of species, especially those plant parts that are closely related or have similar morphological or chemical structures. In addition, the use of traditional medicines can delay the application of effective treatments or even lead directly to adverse reactions.

The example of LHQW from the above article remains. The therapeutic effect of TCM usually comes from the synergistic effect of certain ingredients, the efficacy and safety of which are more difficult to assess.[9] The development of its research and development has been seriously hampered by the lack of clear standards and measurement criteria. In addition, poor clinical trial data often makes TCM and its formulations technically non-compliant with international standards, and therefore unable to obtain intellectual property protection when entering global competition. Requiring traditional medicines to meet the testing standards of modern medicine can therefore be a serious obstacle to their use.

4.3. The Dilemma of Patent Protection of Traditional Medicine Knowledge

4.3.1. Selection of Disclosure

The issue of patent disclosure raises a number of complex dilemmas in the discussion on the protection of traditional medicinal knowledge. Overprotection of traditional medicines can lead to increased costs and limited access to these resources. The development of traditional medicines is hampered by the lack of knowledge development capacity in countries where many traditional medicine resources are located.[10] However, disclosure of traditional medicine knowledge can undermine its novelty and make it more difficult to patent.[10]

Some countries want to reduce the likelihood of misappropriation through systematic disclosure. India, for example, is developing a "Digital Library of Traditional Knowledge," an electronic database designed to make traditional knowledge that is already in the public domain easily accessible and searchable. However, registration still creates barriers to intellectual property protection for undisclosed traditional knowledge, particularly in terms of patent protection. Disclosure of such knowledge may prevent future patent applications, especially if the holder of the knowledge has not explicitly chosen whether or not to disclose it.

4.3.2. Bioprospecting Issues and Misappropriation of TMK

Bioprospecting is a form of access to genetic resources, a process aimed at finding new products of potential value based on biological resources and traditional knowledge, and then commercializing these new products. And bioprospecting is often followed by knowledge theft. This is because the process of bioprospecting involves developed countries or companies taking these resources or knowledge from developing countries or indigenous communities, but exploiting, reproducing, disseminating or commercializing this traditional medical knowledge without permission or fairness and without due recognition and benefit sharing with indigenous or local communities.[11]

Several TNCs and research institutes also patent and commercialize traditional medical knowledge and biological resources by exploiting them without patent protection. One example is the case of turmeric in India. The root of the turmeric plant (Curcuma longa) is an important medicinal herb in Indian Ayurvedic medicine. It is used to treat a variety of ailments such as anemia, asthma, burns, conjunctivitis, and diabetes, etc. In 1995, two Indian scientists at a U.S. university were granted a U.S. patent for their use of turmeric in the treatment of wounds. This was challenged by an Indian research organization, which argued that it was traditional Indian medical knowledge, and finally succeeded in overturning the patent in 1997. This case is also believed to be the first instance of a successfully overturned biopiracy patent.

In many cases, TK holders may not be aware of how their knowledge is being used, making it difficult to effectively implement benefit-sharing mechanisms. They also often lack the legal resources and knowledge to effectively protect their rights and interests. Even when misappropriation is detected, the process of pursuing legal remedies can be time-consuming and costly. In addition, the current international legal framework provides inadequate protection mechanisms for traditional knowledge, which puts these holders at a disadvantage when competing with large multinational corporations.

5. Suggestions for Patenting Traditional Medicine and International Case Studies

5.1. Improving the Domestic Bill on Traditional Medicine Patents

It is recommended that countries enact legislation on patent protection specifically for traditional medicines and explicitly provide that traditional medicinal knowledge can be the subject of patent applications. The legislation should first define "traditional medicine", which should be broad and inclusive, covering a wide range of forms of traditional medicinal knowledge, such as herbal medicines, acupuncture, tuina, traditional healing methods, traditional medicinal formulas and so on. Such legislation should include a specific patent application procedure, the scope of protection and the duration of patent rights to ensure that traditional medicinal knowledge receives adequate legal protection.

China has very good experience in this area, which can serve as a reference for other countries. In China, the Chinese Medicine Act was enacted in December 2016 to provide specific legal regulation on issues related to Chinese medicine.[12] In addition to establishing safety standards for TCM and its ingredients, the law promises that TCM and Western medicine will enjoy equal status in the government-run healthcare system, thus eliminating the relative disadvantage of TCM compared to Western medicine.[3] The new law details the establishment of a sound regulatory system for Chinese medicine, the protection of intellectual property rights, the social operation of medical services, and the quality control of the entire supply chain of medical materials. In addition, the Regulations on the Protection of Chinese Materia Medica stipulate that the protection period for Class I Chinese herbal medicines is 30 years and Class II Chinese herbal medicines is 7 years, and that the categorization will be administered by the State Administration of Traditional Chinese Medicine.[13] In addition, China grants owners of TCM knowledge the right to inherit and use that knowledge. Owners of some classic formulas containing secret ingredients and production techniques can apply for intellectual property protection.

In addition, in the actual legislative process, each country should also take into account the specific situation of its own country and the characteristics of the development of traditional medicine, and formulate special guidelines for patent applications for traditional medicine, providing specific cases to illustrate how to demonstrate the uniqueness and innovation of traditional knowledge in patent applications. This will help applicants to better articulate the innovative nature of the knowledge. And more program support will be given to traditional medicine researchers so they can conduct more clinical trials to pass safety tests and address the problem of inadequate evidence of efficacy.

5.2. Establishment of an Electronic Archive for Recording TMK

Documentation of TMK is essential for the preservation of traditional medicine. Today, as the culture of Aboriginal communities fades and some of the channels for transmitting traditional medical knowledge disappear, documenting TMK

can help these groups preserve this knowledge for future generations. In addition, documenting TK can help to defensively protect traditional medicine from third parties who may inappropriately access TK-related intellectual property. In India, the aforementioned case of turmeric is launching the Traditional Creative Path Knowledge Digital Library (TKDL).[4] It aims to organize the existing literature on the four traditional Indian systems of medical knowledge - Ayurveda, Unani, Siddha and Yoga - and prevent the patenting of existing knowledge. Such a database will enable patent officials around the world to search and review all commonly used knowledge and thus prevent the erroneous granting of patents based on public domain knowledge. China has also established a TMK database to protect against knowledge theft. In China, the National Institute of Traditional Chinese Medicine Information has established the largest TCM database in China, the Traditional Chinese Medicine Database, which contains about 48 sub-databases and 120,000 TCM-related records.[2]

However, there are some drawbacks to documenting TMK. First, if the database is freely available to the public, it may become part of the public domain, with the risk that the knowledge may be disclosed to third parties. In addition, this may result in the TMK owner not having full control over the TMK in the database and may result in the inability to protect the TMK trade secrets or obtain patent protection. In addition, public disclosure of the knowledge may result in the use of the TMK without the authorization of the TMK holder.[4] Nevertheless, the creation of electronic archives remains an important step in advancing research on the safety and efficacy of TK, contributing to clinical practice and the development of educational materials, and encouraging investment and innovation in traditional medicine.

5.3. Establishing Access and Benefit-Sharing Mechanisms

The Nagoya Protocol [14] emphasizes that holders of traditional knowledge should receive fair and equitable benefit-sharing when their knowledge is used. This could be applied to traditional medicines to ensure that indigenous or local communities receive appropriate benefits when traditional medicinal knowledge is researched, developed or commercialized. A collective patent application system could be established to address this issue. Allowing communities to register their traditional medicinal knowledge not only helps to document the source of that knowledge, but also serves as a supporting document for future patent applications, helps to confirm the legitimacy of the applicant, and ensures the interests of the patent holder.

Peru is a model for other countries in protecting the intellectual property rights of indigenous peoples. In Peru, the powder, capsules, and various health products made with Maca as the main raw material are sold in large quantities in markets such as the United States, Japan, and Europe, generating huge foreign exchange earnings. To protect the interests of indigenous peoples, in 2002 Peru enacted the Law for the Protection of the Collective Intellectual Property Rights of Indigenous Peoples. The collective knowledge protected by the law is characterized by two things: first, it belongs to the indigenous community and not to individuals; and second, it is passed down from generation to generation, cannot be taken away or abandoned, and is legally registered by the government. Under the law, anyone wishing to access collective knowledge for scientific, commercial or other purposes must obtain the informed consent of the indigenous representative body of the collective knowledge, on the basis of which a licensing agreement must be signed between the two parties. This program strongly protects the interests of Peru's indigenous peoples based on traditional medicinal knowledge and prevents the loss of knowledge without compensation.

Peru's Law for the Protection of the Collective Intellectual Property Rights of Indigenous Peoples demonstrates how indigenous traditional knowledge can be effectively protected through legislative means, and offers lessons in intellectual property protection for other indigenous groups around the world. Through cooperation and support, the international community can help more countries and regions protect their indigenous knowledge and cultural heritage.

6. Conclusion

The interface between patent law and traditional medicine is one of those extreme sensitivity. With the growing realization in global communities about the value represented by traditional medical knowledge, there is a hue and cry for an intellectual property framework that can both safeguard and at the same time respect the knowledge, balancing out various interests. The current international regimes are mainly in the form of the PCT, the CBD, and the TRIPS. They do offer support for mechanisms to be adopted for the safeguarding of TMK. At the same time, they expose many deficiencies in relating to TMK as collective, cultural, and often-unrecorded knowledge.

The main challenges facing traditional medical patent applications include issues of novelty, inventiveness and determination of drug safety. Some of these issues are biopiracy and misappropriation of TMK, indicating the need for country-specific legislation. Two countries, China and India, have made great strides in developing national laws and databases to protect TMK, and Peru's collective protection could serve as a potential model for other countries. What is needed, however, is a stronger and globally harmonized approach to ensure that TMK holders are fairly recognized.

In conclusion, therefore, a lot still needs to be done in affecting the integration of traditional medicine within the global intellectual property law framework. It will require new legal instruments, full documentation systems, and dedication to equitable benefit-sharing arrangements. Just then will the global community be better placed to protect traditional medicine, thereby ensuring that its benefits are saved and respected for future generations.

Acknowledgments

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