



ABS Mechanism of Traditional Chinese Medicine Knowledge from the Perspective of Law

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Abstract. Traditional knowledge of Chinese medicine is the essence of the Chinese nation, and it is the internal core of the inheritance and development of traditional Chinese medicine culture. The owner of traditional Chinese medicine has the right to inherit and use the traditional Chinese medicine knowledge held by him, and has the right to know the agreement and benefit sharing for others to master and use the traditional Chinese medicine knowledge owned by him. This paper aims to analyze the current situation of the legal protection of traditional Chinese medicine knowledge in China, understand the existing domestic laws and regulations, explore and summarize the difficulties faced by the protection of traditional Chinese medicine intellectual property rights in China, and compare the benefit sharing mechanism of traditional knowledge in the world, so as to explore how the owner of traditional Chinese medicine knowledge can safeguard the benefit sharing right under the current background, and clarify the object and subject of traditional Chinese medicine knowledge rights, Change the current situation that traditional Chinese medicine knowledge has been defined as “public heritage of mankind” for a long time and is occupied and utilized free of charge, so as to further improve the exchange mechanism of traditional Chinese medicine knowledge and promote the inheritance and development of traditional Chinese medicine knowledge.

Keywords: ABS mechanism · Chinese medicine · traditional knowledge · law

1 Introduction

Traditional knowledge of traditional Chinese medicine refers to the theories, skills, and symbols of traditional Chinese medicine based on the long-term practice of the Chinese nation, inherited from Test methods, diagnostic skills, traditional Chinese medicine processing skills, pharmaceutical methods, health care methods, etc. Although the preservation of traditional intellectual property rights has become a global consensus, the protection of traditional intellectual property rights of traditional Chinese medicine is still not satisfactory, because the current Chinese patent legal system only guarantees the creation of achievements, not the source of resources. Therefore, only by protecting the traditional intellectual property rights of traditional Chinese medicine from the legal root can we promote the innovation and development of Chinese traditional medicine.

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2 Methods

This systematic review and meta-analysis complied with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.

2.1 Search Strategy

We conducted a literature search in PubMed, PsycInfo, Embase and web of science and CNKI of articles that reported the effects of ABS mechanism, benefit-sharing and Chinese medicine on the perspective of law from 2001. The search strategy used Medical Subjects Headings (Chinese medicine) terms and keywords ('ABS mechanism', 'Chinese medicine', 'traditional knowledge', 'law').

2.2 Selection Criteria

All the abstracts from the initial search were independently screened by OA against the following selection criteria. Any doubt about meeting/not meeting the selection criteria was resolved by reviewing the full article.

2.3 Statistical Analysis

Individual effect sizes (Cohen's d) for control and intervention conditions of each RCT were calculated with reported means and standard deviations using the effect size calculation software developed by Wilson (2010).

3 Result

3.1 The Status Quo of Legal Protection of Traditional Knowledge of Traditional Chinese Medicine in China

3.1.1 The Relevant Domestic Legal System is Being Gradually Explored and Established

On February 12, 2016, the "Outline of the Strategic Plan for the Development of Traditional Chinese Medicine (2016–2030)" issued by the Government Office of the State Council. It affirms the significance of traditional Chinese medicine, and clearly proposes to comprehensively inherit, develop and use traditional Chinese medicine. In October 2019, the CPC Central Committee and the General Office of the State Council issued the "Opinions on Promoting the Inheritance, Innovation and Development of Traditional Chinese Medicine". It is also pointed out that the current traditional Chinese medicine has not been fully inherited, developed and used completely.

On January 22, 2021, the "Several Policies and Measures on Accelerating the Development of Traditional Chinese Medicine Characteristics" issued by the General Office of the State Council encourages the realization of Chinese and Western medicines with the same effect and the same price. In order to thoroughly implement the "Opinions of

the Central Committee of the Communist Party of China and the State Council on Promoting the Inheritance, Innovation and Development of Traditional Chinese Medicine”, promote the dissemination of traditional Chinese medicine culture, and make traditional Chinese medicine a social and cultural awareness for the people to improve their physical and mental health. On June 29, 2021, China’s Traditional Chinese Medicine Administration, the Central Propaganda Department, the Ministry of Education, the National Health Commission, and the State Administration of Radio, Film and Television jointly formulated the “Traditional Chinese Medicine Culture Communication Action Implementation Plan (2021–2025)”.

On October 25, 2021, in order to protect traditional Chinese medicine culture, in accordance with the relevant provisions of the “Chinese Medicine Law of the People’s Republic of China”, China’s traditional Chinese medicine management agency took the lead in formulating the “Regulations on the Protection of Traditional Chinese Medicine Knowledge”. In January 2022, the Office of the Inter-Ministerial Joint Conference on the Implementation of the State Council’s Intellectual Property Strategy issued the “Outline for Building a Strong Intellectual Property Country and the Annual Promotion Plan for the Implementation of the 14th Five-Year Plan”, identifying seven areas to promote the construction of a strong national intellectual property country. Fifteen important goals and specific measures, which require the protection of traditional knowledge of traditional Chinese medicine.

On March 29, 2022, the State Council issued the “Notice on the “14th Five-Year Plan” for the Development of Traditional Chinese Medicine, and pointed out that: by 2025, the public service capacity of the traditional Chinese medicine health system will be significantly improved, and the high-quality development policy of traditional Chinese medicine will be implemented. The measures and system will be more perfect, the revitalization and development strategy of traditional Chinese medicine has made positive progress, and the role of local characteristics in the development of the health country will be further brought into full play.

3.1.2 Difficulties in the Protection of Intellectual Property Rights of Traditional Chinese Medicine Culture

Protection of intellectual property rights and benefit-sharing are key issues for all ethnopharmacological research [2]. China’s intellectual property system has not been established for a long time, and it has indeed played a certain role in preserving the downstream development achievements of traditional Chinese medicine, such as Chinese patent medicines, processing and useful extraction of traditional Chinese medicines, etc. However, its downstream research results do not fully cover the development of traditional Chinese medicine. Field. It includes traditional traditional techniques in Chinese patent medicine, such as processing and distillation. The main source of traditional Chinese medicine, such as traditional Chinese medicine works, is difficult to be included in the modern intellectual property protection system due to the characteristics of long-term production, complex subjects, and many objects. However, the cultural achievements of traditional Chinese medicine are mainly created by ancient Chinese in ancient times and have a long history. They have long passed the protection period of modern intellectual property laws and gradually moved towards the public domain. Existing legal systems

have many drawbacks and they cannot effectively prevent the loss of genetic resources [4].

Several UN policy processes are embracing a calcified approach to conservation and equity in science [13]. The owner's patent awareness is not high, and Chinese medicine companies also lack attention to traditional Chinese medicine patents. On the other hand, due to the influence of traditional Chinese culture, some well-known traditional Chinese medicine companies have passed down the traditional secret recipes obtained after long-term medical scientific research, only through the family, thinking that the method of publicity in exchange for protection will lack the traditional characteristics of our country. However, many people do not agree with the international standards of traditional Chinese medicine, and even doubt the scientific and technical nature of traditional Chinese medicine inheritance knowledge, and allow the inheritance of intellectual property rights to be lost or even mutated. At the same time, many traditional Chinese medicine enterprises have also appeared the status quo of attaching importance to the market and ignoring protection, and investing too little in the intellectual property rights of traditional Chinese medicine. Countries are nevertheless acting unilaterally on placement of genetic resources as their sovereign right to exploit [12]. According to relevant statistics, the current national Chinese medicine enterprises' investment in patents only accounts for about 3% of the total revenue of their main business, while foreign related investment has reached more than 10%. China currently lacks a policy and regulatory system for access and benefit sharing (ABS) to its genetic resources [10].

Due to the lack of national scientific and technological investment and research on traditional Chinese medicine, China's innovation capability in the field of biotechnology is relatively insufficient. Different from the "blooming everywhere" of Western medicine research, the field of Chinese medicine research in China is rarely mastered by foreigners. According to the World Health Organization (WHO) data, about 60% of Chinese people in the world are currently using traditional Chinese medicine to cure diseases, and the average annual global sales of traditional Chinese medicine has exceeded 16 billion US dollars. Seventy to eighty percent of the traditional Chinese medicine products used in foreign countries are purchased from China, but the proportion of Chinese patent medicines directly imported by them is less than 30%, and the rest are raw materials. And the price is relatively low. In the field of international application of Chinese medicine invention patents, although foreign applicants have submitted more than 10,000 invention patents in China, the number of patent applications submitted by Chinese overseas is much smaller. This also shows the shortage of scientific and technological innovation of traditional Chinese medicine in my country, most of the countries are still in the stage of repetition at a low level, and this problem also endangers the national protection of traditional Chinese medicine intellectual property. Advanced countries such as the United States, Japan and South Korea rely on strong R&D strength and cutting-edge biological science and technology to actively screen traditional Chinese medicine knowledge and research new pharmaceutical raw materials to obtain effective active ingredients and apply for patents. Although my country has become the birthplace of traditional Chinese medicine in the world, due to the lack of scientific research and innovation and the imperfect knowledge system, it has to become the main provider of raw materials

and watch a large number of intellectual property achievements of traditional Chinese medicine lost.

3.2 International Benefit-Sharing Model of Traditional Knowledge Resources

The most basic form of licensing fee is the registration and recognition mechanism. For example, Paragraph 8 of Peru's 2002 Law on the Establishment of a System for the Protection of Collective Knowledge of Indigenous People's Biological Resources expressly stipulates that at least 10% of the pre-tax life value of the total sales volume of goods developed based on collectively owned intellectual property rights should be provided to the Indigenous Peoples Development Foundation, while Article 27(c) expressly stipulates that the economic compensation received by Indigenous people for the use of their society's collective intellectual property rights shall include the initial currency or other appropriate benefits to promote their sustainable economic development, the ratio of which shall not be Less than 5% of the pre-tax life value of the total sales volume of goods developed directly or indirectly based on collectively-owned intellectual property rights, as the case may be. Although this revenue-sharing model that requires restrictive clauses also has a relatively effective legal binding force, and its distribution is based on the benefits generated by the use of traditional knowledge, it is relatively suitable, but it is easy to become a mere formality and get out of control.

A socially equitable benefit-sharing method based on case-by-case coordination and agreement, simplified access to GR shall be granted by the provider countries for non-commercial biodiversity research [3]. For example, The three objectives of the Convention on Biological Diversity (CBD) are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefit arising from the utilization of genetic resources [1], which provides for the development of a benefit-sharing approach by interested parties through the identification of research parameters, areas of use, sustainability, environmental impacts, and desired outcomes. The level and other factors are consulted, and the number of benefits is basically finalized on a case-by-case basis, and the time frame of short-term, medium-term or longer-term benefits is determined according to the specific content of the case-study method. Using this model is obviously a contract management model under the authorization and guidance of the state, but it strengthens the freedom of contract and the participation of state executive power to a considerable extent.

There are rich genetic resources and associated traditional knowledge in the vast territory of ethnic minority areas in the country [5]. Consumers of traditional Chinese intellectual property rights will help the owners of traditional Chinese intellectual property rights to develop infrastructure, provide research funds or set up research organizations, provide support for teaching and training, etc., establish databases and research related to traditional Chinese intellectual property rights protection Organizations, museums, etc., organize funds or develop management support, etc. For example, SHAMAN Pharma Co., Ltd. of San Francisco, California, United States integrates Native American experience, modern science, and principles of social reciprocity into innovative drug development programs. The profit-sharing system established by the enterprise involves short-term, medium-term and long-term reciprocal arrangements. Short-term compensation projects include the construction of the runway at the Ecuadorian Amazon airport,

the holding of public lectures and forest conservation seminars, the provision of direct health care services to the cooperating societies, and the supply of clean water systems to the cooperating societies of Ecuador and Indonesia. The medium-term arrangement is mainly to provide scholarships and research and development expenses for researchers engaged in the application of traditional Chinese medicine, and also to build infrastructure for the community's scientific research and development. As an important part of its long-term strategy, the group has also established a non-profit group of Medicinal Forest Conservation, dedicated to the protection of cultural and ecological diversity, and responsible for the conservation of natural and ecological human resources that are part of the heritage of indigenous peoples. Research and management work. This profit model mainly realizes revenue sharing through the compensation method of non-monetary benefits, but no matter which specific form is adopted, it is formed after fully considering the interests of traditional intellectual property holders and the commercialization of traditional intellectual property rights. Stipulates parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism [11]. Through the use of certain non-monetary compensation methods for the relationship between real economic values, holders can get a reasonable share that can be recognized by all parties. This way of compensation is often based on the national interest as the main recipient, and directly benefits the entire indigenous community. Designing efficient ABS provisions turns to be highly complex given its multi-task and multi-agent problem structure [8].

Foundation initiated and jointly organized and operated by representatives of users and holders of traditional cultural intellectual property rights (or from different holders), and will use traditional cultural intellectual property rights after commercialization. The corresponding shares of the income formed are assigned to the society, and the society will use the fund in accordance with the corresponding legal norms or regulations. Therefore, the Kani Tribal Social Trust Fund was established in Kerala in 1997, and the TBGRI agreement provides a 50% rate of drug license fees and royalties based on human genetic resources development and research as a fund management method. The establishment of a trust society's participation, sharing and distribution of due income management model is especially suitable for the special situation where traditional knowledge holders originate from different sovereign or geographical ministries or nations.

The Access and Benefit Sharing is very important for biodiversity [14]. A revenue sharing system that combines guaranteed revenue sharing in the terms of the agreement with compensation for unlicensed losses. For example, according to Chapter 7 of Brazil's "Provisional Regulations for the Protection of Biological Diversity and Genetic Resources" in 2001, in addition to the method of entering into a contract to ensure that Brazil, which is a party to the contract, participates in the sharing of varieties and uses of traditional knowledge through federal laws in a fair and legal manner. In addition to the economic benefits arising from technology and economic development activities, the responsible party shall be liable for damages for business and development activities that fail to use the acquired traditional knowledge in accordance with the requirements of laws and regulations, and further develop its varieties and technologies. The amount shall not be less than 20% of the net income from the sales of the product or 20% of the net income obtained from the license fee after the responsible person authorizes the variety, method or technology to a third party, regardless of whether the patent protection

is obtained; compensation does not affect Appropriate administrative penalties and corresponding financial penalties may be imposed. This is obviously a more comprehensive benefit-sharing criterion, and the function of the state apparatus makes it a protection standard for various legal responsibilities, which can effectively enforce the rights and interests of traditional intellectual property owners. The concept of access and benefit sharing takes these developments into consideration and creates a market for biological resources [15].

4 Discussion

The partnerships between scientists, companies, governments are important [7]. Establish mandatory source disclosure and national prior informed consent systems. Based on the principle of national sovereignty, the benefit-sharing system of traditional knowledge of traditional Chinese medicine should clarify that any foreign enterprises, individuals, or other organizations that obtain research results based on traditional knowledge of traditional Chinese medicine and apply for intellectual property protection such as production licenses or patents in my country must disclose the source and go through Approved by the drug supervision and management department, and at the same time, the violation of the disclosure obligation will be punished, so as to achieve the purpose of spreading traditional Chinese medicine culture through other countries using traditional knowledge of traditional Chinese medicine. In the process of benefit sharing, disputes between individuals and groups are resolved through the contract system; for disputes between different local administrative departments, the common superior Chinese medicine management department can be required to intervene and coordinate, according to the ownership of relevant medical knowledge Status and authorization are processed. A policy arena is constituted through a set of actors with distinct agendas and objectives in one issue area of policy making [9].

The agreement clearly stipulates the benefit plan in currency or non-RMB. Among them, monetary benefits mainly include initial expenses or periodic payments, a certain franchise tax, a certain percentage of sales or profits, relevant professional knowledge or skills acquisition fees or transfer fees, certain fees provided to special social trust funds, A specific amount of scientific research funding subsidies, investment companies' price contributions, etc. Non-monetary benefits also include the development or enjoyment of patents obtained therefrom, unrestricted or restricted business authorizations for goods and services, education and technical training support for employees, R&D cooperation and project research, etc. Provide financial assistance, collaboration and support for the construction and technical improvement of its traditional intellectual property rights holders at all levels in material and management.

The understanding and assessment of environmental impact on heritage assets is of the highest importance for heritage preservation through well-organized maintenance based on proper decision-making [6]. The method of payment of benefits may be divided into two parts: the initial license fee and commercial exploitation, and the share of the subsequent post-development benefits. Determining the payment method of benefits as two parts before and after can ensure that holders of traditional Chinese medicine intellectual property rights can obtain certain benefits while allowing others to commercially use their heritage materials; Guide and promote the rational use and sustainable

development of traditional Chinese medicine inheritance intellectual property rights on a reasonable basis. Specific guiding measures should include short-term compensation, medium-term cooperation, and long-term policies.

5 Conclusion

In the establishment of the relevant mechanism, the Chinese government should be based on the protection and development of traditional Chinese medicine intellectual property rights, ensure short-term compensation for income, pay attention to medium-term strategic development and cooperation, and focus on long-term economic policy stability. Various short-term, medium- and long-term revenue sharing methods can complement each other, so as to achieve common and mutual benefits for the holders and users of traditional Chinese medicine intellectual property rights, as well as spiritual and economic “win-win”.

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