

# Protecting Traditional Chinese Medicine's Traditional Knowledge: an Application Research of Benefit-sharing Right

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## **Abstract:**

The research of this paper helps to effectively protect the utilization of traditional Chinese medicine knowledge and guarantee fair and equitable sharing of the benefits arising from the use of traditional Chinese medicine knowledge. By interpreting the legal meaning of traditional Chinese medicine knowledge protection system in the "Law on Traditional Chinese Medicine", the paper concludes that benefit-sharing right is the core issue in the modern use and protection of traditional knowledge, and then puts forward the design ideas and contents of the application rules for the benefit-sharing rights of traditional Chinese medicine knowledge. Using literature research method and expert consultation method, the paper finds the urgent need to practice benefit-sharing rights of traditional Chinese medicine knowledge. On this basis, the scheme of informed consent and interest sharing of traditional Chinese medicine knowledge is proposed to safeguard the interests of the holders.

**Keywords:** Chinese medicine, Traditional knowledge, Benefit-sharing right, Utilization, protection.

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## I. INTRODUCTION

The World Intellectual Property Organization (WIPO) defines traditional knowledge as: "tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; appearance designs; signs, names and symbols; unpublished information; tradition-based inventions and creations arising in the fields of science, literature or art". Here, "tradition-based" means "knowledge systems, creations, innovations, and cultural expressions passed from one generation to the next in a manner associated with particular peoples and regions, which retain their original connotations and forms despite changes in circumstances."

The traditional Chinese medicine knowledge accumulated by the Chinese nation in the long-term struggle against diseases has been passed down and innovated from generation to generation, forming a system of its own and making outstanding contributions to human health, which is in line with WIPO's definition of traditional knowledge. Then, the protection of traditional Chinese medicine knowledge is the right and responsibility of the people in the place of origin, that is, the holders of the place of origin have the right to inherit and use the traditional knowledge they possess, and enjoy informed consent and

benefit-sharing rights when others acquire, use the traditional knowledge they possess. However, traditional Chinese medicine knowledge mostly enters the public domain and does not belong to the protection scope of the existing intellectual property system design. Hence, some countries and enterprises use advanced technologies and funds to apply for the property rights of substances derived from traditional Chinese medicine knowledge in their host countries by means of duplication, acquisition, cooperation, merger, etc., and then obtain monopoly interests. At the same time, they restrict or even exclude production and sales of Chinese enterprises, which is obviously unreasonable and unfair. Traditional Chinese medicine knowledge can be used by modern technology and continue to serve human health, which is naturally meaningful, but the act of ignoring the origin of traditional knowledge, and freely acquiring and possessing economic benefits brought by the information heritage of the origin obviously betrays justice.

This study is also based on the following factors:

### 1.1 The Need for China to Inherit and Develop the Cause of Traditional Chinese Medicine

Traditional Chinese medicine displays a well-recognized curative effect in the treatment and rehabilitation of COVID-19. According to the data, as of March 13, 2020, 1,261 patients with COVID-19 took "Qingfei Paidu Decoction", and the total effective rate reached 97.78% [1]. "Qingfei Paidu Decoction" is a prescription recommended by the National Health Commission of People's Republic of China and the National Administration of Traditional Chinese Medicine. This prescription is innovated based on "Treatise on Febrile Diseases and Miscellaneous Diseases" written by medical scientist Zhang Zhongjing in the late Eastern Han Dynasty. It can be seen that the information stored in the traditional Chinese medicine knowledge has the "potential energy" to benefit mankind; of course, it also contains huge economic value. In recent years, China has successively issued a series of policies and laws for the development of traditional Chinese medicine. On July 1, 2017, the "Law of the People's Republic of China on Traditional Chinese Medicine" (hereinafter referred to as the "Law on Traditional Chinese Medicine") was implemented. In 2019, the State issued "Opinions on Promoting the Inheritance, Innovation and Development of Traditional Chinese Medicine" and "Opinions on Strengthening the Protection of Intellectual Property Rights", raising requirement of investigating and formulating protection measures in the fields of traditional culture and traditional knowledge to strengthen the protection of intellectual property rights of traditional Chinese medicine. According to article 9 of the "Basic Medical Health and Health Promotion Law of the People's Republic of China" implemented on June 1, 2020, the state shall vigorously develop the cause of traditional Chinese medicine, adhere to the equal emphasis on traditional Chinese and Western medicine, combine inheritance and innovation, and give full play to the unique role of traditional Chinese medicine in medical and health undertakings. On March 29, 2022, the state issued the "14th Five-Year Plan for the Development of Traditional Chinese Medicine" to fully arrange the work of traditional Chinese medicine.

## 1.2 The Need to Protect the Interests of Holders in the Internationalization of Traditional Chinese Medicine

It is an international consensus to protect traditional knowledge. In 2016, China became a party to the "Nagoya Protocol of 'Convention on Biological Diversity' on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from Their Utilization" (hereinafter referred to as the "Nagoya Protocol on Genetic Resources"). As the current intellectual property system cannot effectively protect traditional Chinese medicine knowledge in terms of copyright and patent rights, and the phenomenon of "biological piracy" related to traditional knowledge occurs frequently, the origin of traditional knowledge is greatly harmed both in terms of dignity and economic interests. According to the relevant person in charge of the Medical and Biological Invention Examination Department of the Patent Office of the China National Intellectual Property Administration, taking Japan as an example, the prescriptions for its 210 Kampo medicines are all from China [2]. According to the statistics of the World Health Organization, at present, about 4 billion people in the world use Chinese herbal medicine to treat diseases, and the annual international sales of Chinese medicine is 16 billion US dollars. In front of such a "big cake", Japan gets 80%, South Korea gets 10%, India, Singapore and other countries get 7%, while China, the "originator of traditional Chinese medicine", only gets 3% [3]. In 2018, traditional Chinese medicine entered the international mainstream medical classification standard system historically. By 2021, traditional Chinese medicine has spread to 196 countries and regions around the world, with the total import and export trade of traditional Chinese medicine commodities increased significantly. However, statistics show that many modern Chinese medicines in China have not applied for patents. Application for a patent requires the holder to disclose the prescription, and with slight change on the basis of the disclosed prescription, others will get a new prescription, which will reduce the prescription value. This means that the interests of prescription holders are faced with threats and unfair treatment. Therefore, China has established a traditional Chinese medicine knowledge protection system through traditional Chinese medicine legislation, which clearly defines the right to informed consent and benefit sharing.

## 1.3 The Need for Operability in the Provisions of the "Law on Traditional Chinese Medicine"

Article 2 of the "Law on Traditional Chinese Medicine" stipulates that traditional Chinese medicine refers to the general term for medicine of all ethnic groups in China, including the medicine of the Han nationality and ethnic minorities. Reflecting the Chinese nation's understanding of life, health and disease, it is a medicine and pharmacy system with a long history of tradition and unique theories and technical methods. It can be seen that traditional Chinese medicine is traditional knowledge of medicine with nationality, history, uniqueness, science and inheritance characteristics. It is not only a precious part of the intangible cultural heritage of mankind, but also an important link relating to the interests of the holders behind the current economic globalization competition. Paragraph 2 in Article 43 of the "Law on Traditional Chinese Medicine" stipulates that holders of traditional Chinese medicine knowledge shall enjoy the rights of informed consent and benefit-sharing when others acquire and use the traditional Chinese medicine knowledge held by them. However, such macro-conceptual guidance lacks operability, so it is necessary to study and design the composition and implementation procedures of its legal

relationship, as well as the rules of supervision and protection, so that the benefit-sharing rights can be effectively implemented.

## **II. LEGISLATIVE PROVISIONS ON PROTECTION OF TRADITIONAL CHINESE MEDICINE KNOWLEDGE**

The "Law on Traditional Chinese Medicine" stipulates the protection of traditional Chinese medicine knowledge in Article 43 of "Chapter VI Inheritance and Cultural Dissemination of Traditional Chinese Medicine", which consists of three paragraphs: Paragraph 1 is that the state should establish a database, a protection list and a protection system for the protection of traditional Chinese medicine knowledge; Paragraph 2 is that holders of traditional Chinese medicine shall have the right to inherit and use the traditional Chinese medicine knowledge held by them, and have the right of informed consent and benefit sharing when others acquire and use the traditional Chinese medicine knowledge held by them; Paragraph 3 is that the state should implement special protection of the composition and production process of traditional Chinese medicine prescriptions legally recognized as state secrets. It can be seen that paragraphs 1 and 2 have a progressive relationship, while paragraph 3 and paragraphs 1 and 2 have a special-general relationship, and the benefit-sharing right stipulated in paragraph 2 is the core issue, while a certain degree of correlation is displayed between the paragraphs.

Paragraph 1 stipulates the establishment of a protection database and a protection list system, which are the preconditions for the implementation of the right to informed consent and benefit-sharing. Traditional Chinese medicine knowledge includes: theoretical knowledge (i.e. traditional health care, disease prevention knowledge and methods such as life and health theory, disease and prevention theory, medicine and prescription theory); diagnosis and treatment techniques; traditional knowledge and methods of collection, cultivation, storage, processing and identification of traditional Chinese medicinal materials; traditional prescriptions and preparations; traditional signs, symbols, images and words of traditional Chinese medicine; etc. [4]. It can be seen that its protection involves a huge systematic project, and the state is the natural subject of the project. Since 2013, the National Administration of Traditional Chinese Medicine has set up the project of "Technical Research on Traditional Chinese Medicine Knowledge" to carry out the diagnostic survey, screening and confirmation of traditional Chinese medicine knowledge. The traditional Chinese medicine knowledge projects meeting the inclusion criteria are registered and filed. In addition, the traditional Chinese medicine knowledge protection database and protection list have been established, and 32 ancient books on prescriptions before the Sui and Tang Dynasties have been included, with more than 38,000 prescriptions in total [5]. These works have laid a solid foundation for the effective protection and transformation of traditional knowledge.

Paragraph 2 stipulates that it is necessary to combine the "Nagoya Protocol on Genetic Resources" to ensure that holders of traditional Chinese medicine knowledge have the right to informed consent and benefit sharing when others acquire and use the traditional Chinese medicine knowledge held by them. The "holders of traditional Chinese medicine knowledge" here include natural persons, groups, holding units and other legal person organizations and unincorporated organizations, that is, individuals, families,

specific regional groups (ethnic gathering places, villages), apprentice groups, schools, time-honored enterprises, medical institutions, etc. holding traditional Chinese medicine knowledge such as active traditional Chinese medicine diagnosis and treatment techniques, experienced prescriptions, Chinese herbal medicines, preparation methods, etc.

Paragraph 3 provides special protection for the composition and production process of traditional Chinese medicine prescriptions legally recognized as state secrets to ensure that it does not enter the field of public knowledge through long-term secrecy. At present, Pien Tze Huang (the formula and production process are both top secret) and Yunnan Baiyao are the only two national first-class protected Chinese medicine varieties in China, which are top "state secrets" [5]. According to the "Law of the People's Republic of China on Protection of Secrets", the confidentiality period of top secret shall not exceed 30 years. If it is necessary to further maintain confidentiality, the confidentiality period shall be re-determined and extended before the original confidentiality period expires. This provision helps to protect the resources of special traditional Chinese medicine varieties and protect the interests of holders from being infringed.

It can be seen that the establishment of the traditional Chinese medicine knowledge protection database and protection list provides a basis for the inheritance and use, implementation of the holder's informed consent and benefit-sharing rights, but it also limits the inheritance and use, informed consent and benefit-sharing rights. Objectively, traditional Chinese medicine knowledge is extensive, historical, regional, folk, secret, etc., so it is difficult to find a sweeping approach. In addition, for traditional Chinese medicine under special protection of state secrets, as long as it is kept secret, there is no room for informed consent and benefit-sharing rights. If it is not during the confidentiality period, the right to informed consent and benefit sharing also applies. Therefore, it is crucial to establish a system of rules on the universal application of benefit-sharing right to protect and use traditional Chinese medicine knowledge.

### **III. APPLICATION AND PROTECTION RULES DESIGN FOR BENEFIT-SHARING RIGHTS IN TRADITIONAL CHINESE MEDICINE KNOWLEDGE**

Traditional Chinese medicine is the original medicine of the Chinese nation. Facts have proved that its traditional knowledge has high active health, technology, economy, culture and ecological values. The key to its protection is the implementation of benefit-sharing rights. The author believes that China should formulate special "Regulations on the Protection of Traditional Chinese Medicine Knowledge" to improve or refine specific models, use methods and safeguard measures for its traditional knowledge database, protection list and benefit-sharing rights system.

#### **3.1 Specify the Principle of National Sovereignty that Traditional Chinese Medicine is Biological Genetic Resource**

The "Convention on Biological Diversity" provides the international legal basis for the protection of biological genetic resources, and establishes three basic principles for the utilization of biological genetic

resources: economic sovereignty over biological genetic resources; prior informed consent to obtain biological genetic resources; the benefit-sharing principle for the use of genetic resources. Signatories to the convention include 195 countries and the European Union. Hence, "source disclosure requirement, benefit sharing, and respect for providers" should become the universal principle of the "Regulations on the Protection of Traditional Chinese Medicine Knowledge". It is necessary to state ownership rights of traditional Chinese medicine knowledge externally, that is, holders of traditional knowledge should be respected and recognized. This lays the foundation for preventing unjust enrichment and unfair sharing and realizing fair sharing of benefits among stakeholders.

### 3.2 Implementation Conditions for Providing the Right to Benefit from Traditional Chinese Medicine Knowledge

Traditional Chinese medicine knowledge has the characteristics of intellectual property rights such as immateriality, exclusiveness and regionality. The current trademark system and geographical indication system of intellectual property rights are basically applicable to the protection of traditional knowledge, but due to their non-novelty and other characteristics, it is difficult to apply the patent system protection. Therefore, the national and local governments should extensively and continuously collect, sort, screen and confirm the living traditional Chinese medicine knowledge, and register, file, enter the projects meeting the selection criteria into the database and expressly publish them, so that the disseminators, users abide by the obligations of prior informed consent, access and benefit-sharing. In this way, users know how to obtain traditional knowledge through legal channels.

First, it is necessary to establish a national departmental coordination mechanism and specialized management agency for the acquisition and benefit-sharing of traditional Chinese medicine knowledge, which not only organizes, but also monitors and tracks the use. The regulatory authority should provide the public with a platform or multi-party system for the display of traditional Chinese medicine knowledge to facilitate access to traditional knowledge by disseminators and users. Also, communication channels should be provided for fair and reasonable sharing of benefits arising from the use of such knowledge on a complementary and mutually reinforcing basis. From the legal point of view, this defines the subject status, object scope and rights content of traditional knowledge, thereby determining the value needs of stakeholders as well as their contribution and role in the inheritance and utilization of traditional knowledge, and also clarifying the preconditions or conditions, methods and guarantees for benefit-sharing right. That is to say, in terms of subjects, the method of obtaining qualifications, the criteria for defining private rights subjects and public rights subjects, and the status of each subject in obtaining benefit-sharing decisions, etc., are specified. In terms of objects, the constituent elements and scope of traditional Chinese medicine knowledge are specified. In terms of the content of rights, it specifies the proportion of benefits that the providers of traditional knowledge can equitably share from the results of research and development or the interests obtained from commercial and other use. As far as the protection and utilization of the theoretical system of traditional Chinese medicine knowledge is concerned, entering it into the database and publishing it allow protection from the source. For example, the family of Dihuang Pills is derived from the addition and subtraction of Liuwei Dihuang Pills. Even the "principle and

method" of preparing Liuwei Dihuang Pills are well protected, "prescription and medicine" for Qiju Dihuang Pills, Zhibai Dihuang Pills, Guishao Dihuang Pills, etc. will appear [6]. In other words, if only "prescription and medicine" are protected, but "principle and method" are not protected, then the source of innovation will be blocked. Hence, regarding the classic prescriptions of traditional Chinese medicine, it is necessary to form overall protection and utilization "running throughout the process".

Second, it is necessary to establish a prior informed consent procedure for obtaining traditional Chinese medicine knowledge, an international certificate system for source disclosure and an intellectual property system. [7] Subjects using traditional Chinese medicine knowledge should obtain the prior informed consent of traditional knowledge holders. This is an obligation for the user, a right for the holder, a manifestation of respect for the holder's personal interests, and a prerequisite for the sharing of economic interests. "Prior" is a temporal constraint. The user's obligation to explain and seek consent must be completed before the actual acquisition of traditional knowledge, and any subsequent remedial actions are considered invalid. The competent authority of the country to which the traditional knowledge belongs has the right to punish those without informed consent, and refuse to recognize the patent rights derived from the research results of the act. The precondition of "consent" is "informed", that is, the holder or the relevant supervisor must express the intention of consent under the condition of full knowledge. The core of "prior informed consent" is "consent", that is, the acquisition and utilization of any traditional knowledge must require the prior consent of the holder. Otherwise, it is an infringement of the sovereignty of others or other countries. In addition, the use subject must comply with the source disclosure obligation, especially for commercial use behavior. This obligation is mandatory and one-way, which reflects respect and recognition for traditional knowledge holders. The obligation of source disclosure is also a form of publicity, which can guarantee its objective presentation in terms of authenticity, accuracy, completeness and also acceptance of public supervision.

### 3.3 Construct a System of Application Rules for the Benefit-sharing Rights of Traditional Chinese Medicine Knowledge

Whether the rights can be implemented requires normative guidance, and there is a risk of moral hazard or anomie. Therefore, it is necessary to design an application system for the benefit-sharing right of traditional Chinese medicine knowledge to clarify rights, obligations, and responsibilities.

With the help of copyright system rule design, the benefit-sharing rights of traditional Chinese medicine knowledge is divided into a dual structure of personality interests and property interests according to the institutional classification of personality rights and property rights, which can also correspond to the obligation of information disclosure. The rule design for property interests sharing can also be based on the rule design of the patent: the conditions and procedures for the two methods of agreed use and statutory use, including licensing, statutory license, compulsory license, fair use and other utilization methods, and the handling of bona fide use without agreement and statutory permission. In the spirit of the contract, the holders or providers of traditional Chinese medicine and users shall negotiate on an equal footing, confirm the benefits and determine the proportion of benefits from the research and

development results or the benefits obtained from commercialization and other uses. Agreement should be obeyed if there is an agreement, law should be obeyed if there is no agreement. The content design should give consideration to users' motivation and incentives to comply with the regulations on benefit acquisition and sharing. Under the guidance and coordination role of the government, in order to emphasize the diversification and multi-level interests between the rights individuals and various stakeholders, the parties can be encouraged to sign contracts on sharing through model contracts [8], which can effectively implement prior informed consent system, mutually agreed terms, source disclosure system, etc.

In the case of malicious use of traditional knowledge without prior informed consent, such as plagiarism, unauthorized offensive use, false source declaration or concealment of source, etc., it belongs to tort liability, and the principle of attribution should adopt the principle of fault, and the main responsibility should be civil liability, which may be supplemented by other sanctions if conditions permit. It is also possible to link the protection of traditional Chinese medicine knowledge with the protection of intellectual property rights through the provisions of the domestic "Patent Law" on the obligation to disclose the source of genetic resources. That is, no patent right shall be granted for act of acquiring or utilizing traditional knowledge in violation of laws and administrative regulations, as well as inventions and creations completed relying on the traditional knowledge. The direct source and original source of the traditional knowledge utilized or involved must be disclosed in the patent application, and the reasons shall be stated if the original source cannot be explained. In case of no disclosure or provision of incorrect information, the patent application can be rejected or the patent can be declared invalid.

#### **IV. CONCLUSION**

Article 3 of the "Law on Traditional Chinese Medicine" stipulates that, "The cause of traditional Chinese medicine is an important part of national medical and health undertakings. The state should vigorously develop the cause of traditional Chinese medicine, implement the policy of paying equal attention to traditional Chinese medicine and Western medicine, establish a management system that conforms to the characteristics of traditional Chinese medicine, and give full play to the role of traditional Chinese medicine in national medical and health undertakings." It can be seen that the state has established the strategic position of traditional Chinese medicine in the national economic and social development in the name of law. Every country in the world has the right to design intellectual property rights and sovereignty in line with its own social, economic and cultural environment according to the advantages of its own knowledge resources, knowledge inheritance and innovation status. Today's developed countries enjoy this freedom of design in original development, and this freedom has made positive contributions to their economic development, which is an indisputable historical fact. In the face of the competitive situation of economic globalization and the unjust use of traditional knowledge caused by the existing intellectual property system, China needs to make the application and protection of the informed consent and benefit-sharing rights of traditional Chinese medicine instructive or practical to safeguard the interests of the holder.



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