Review

Evolution of the protection system for traditional Chinese medicine varieties and the strategic responses of traditional Chinese medicine enterprises

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Abstract

The protection system for traditional Chinese medicine (TCM) varieties, as an important policy tool to promote the development of TCM, has a long history of over 30 years, from the promulgation of the "Regulations on the Protection of Traditional Chinese Medicine Varieties" in 1992 to the comprehensive revision of the draft for soliciting opinions in 2022. The TCM protection system evolves to meet the needs of innovative development of TCM. This paper reviews the policy developments in TCM varieties protection, collates protection data (1993 to 2024), and analyzes enterprises application strategies amid impending regulatory changes.

Keywords: protection of traditional Chinese medicine (TCM) varieties; policy evolution; the exclusive logo of TCM protection; patent and TCM protection integration; intelligent manufacturing and internationalization

As one of the valuable treasures of Chinese culture, traditional Chinese medicine (TCM) plays a significant role in protecting and inheriting cultural traditions. Guided by national policies such as "People's Republic of China TCM Law" [1] and "Protection and Development Plan for Traditional Chinese Medicinal Materials (2015-2020)" [2], the protection of TCM resources and varieties has been incorporated into the national strategic development plan. The protection of TCM varieties is not only crucial for the sustainable utilization of TCM resources but also serves as the best policy support for promoting the continuous improvement of TCM variety quality. Therefore, strengthening the protection of TCM varieties is of great significance for promoting the healthy development and the prosperity of the TCM industry.

In October 1992, the State Council issued Order No. 106 "Regulations on the Protection of TCM Varieties" [3]. Three decades later, in December 2022, the National Medical Products Administration released "Draft Regulations on the Protection of TCM Varieties (for Solicitation

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of Opinions)" [4]. Compared with the existing regulations, the draft proposes many adjustments in terms of protection forms, protection periods, and the rights and obligations of certificate holders. It clarifies that TCM varieties qualifying for protection will receive priority in national essential drug list selection, medical insurance list adjustment, and inclusion in clinical practice guidelines. These enhanced rights underscore the growing significance of TCM variety protection certificates for holders.

This paper reviews the evolution of TCM variety protection policies while systematically analyzing the data of approved TCM variety protection qualifications, protections for the same variety and extended protections between 1993 and 2024. It also analyzes the acceptance data of TCM variety protection in the past ten years from 2015 to 2024. Meanwhile, from the perspective of patent Chinese medicine enterprises, it analyzes how different types of enterprises may strategically position themselves under the new regulations to maximize the value of "TCM variety protection qualification".

1 Macro analysis of the evolution of policies for the protection of TCM varieties and the number of approvals

1.1 Policy evolution

In 1992, the State Councilof the People's Republic of China issued Order No. 106, officially promulgating the "Regulations on the Protection of TCM Varieties", marking the formal establishment of the TCM variety protection system in China. On October 10, the same year, the National Committee for the Review of Protected TCM Varieties was established to undertake the technical evaluation of protection of TCM varieties.

This regulation has established the basic purpose of improving the quality of TCM varieties and promoting the development of the cause of TCM. It also requires enterprises producing protected varieties of TCM to improve their production conditions and the quality of varieties.

In February 2009, the General Administration of Food and Drug Supervision issued the "Guidelines for the Protection of TCM Varieties" [5], signifying that the applications for TCM variety protection and extension of protection entered a new period of development. In September 2018, the State Council issued Order No.703, which revised some administrative regulations including the "Regulations on the Protection of TCM Varieties". The drug supervision and administration department was designated as the authority responsible for the supervision and administration of TCM variety protection. The amended Regulations on the Protection of TCM Varieties have been in effect since then and are still implemented today.

This regulation has effectively addressed the key issues within the TCM industry such as excessive number of manufacturers for the same variety, low-price competition, inconsistent quality, and insufficient innovation, yielding positive social benefits. After more than 30 years of implementation, the legislative background has fundamentally changed, and the current regulation is no longer suited to the demands of high-quality TCM development. The incentive effect of protection measures has diminished, resulting in low enthusiasm for applications. Furthermore, there are situations where systems are not connected in the drug registration and full life cycle management system. At the same time, problems such as the absence of an effective exit mechanism, inadequat lingkage with legal systems such as patents, and an overly limited scope of protection targets are becoming increasingly prominent.

In December 2022, the National Medical Products Administration (NMPA) issued the "Draft for Public Consultation on the Revised Regulations

on the Protection of TCM Varieties". This marked the official commencement, after more than 30 years of implementation, of a comprehensive and significant revision of the Regulations.

1.2 Data analysis

According to the National Review Committee for the Protection of TCM Varieties, from January 1993 to December 2023, a total of 7,121 applications for the protection of TCM varieties were accepted, and 1,816 TCM varieties were granted protection status [6].

According to records on the NMPA website, from February 6, 1994 to November 21, 2024, a total of 175 announcements regarding TCM variety protection were made. These comprise 17 announcements by the Ministry of Health, 121 by the State Food and Drug Administration, and 37 by NMPA. Based on these announcements, statistics of the products that obtained the qualification for TCM variety protection were analyzed. The results are shown in Fig. 1.

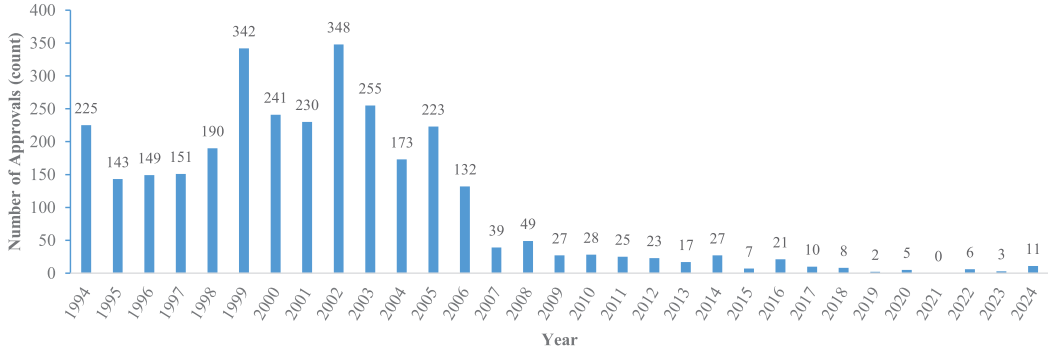

Fig. 1 The number of TCM products under protection from 1994 to 2024

In the ten years from 1994 to 2024, 3110 products received initial protection and protection for the same varieties. The first decade from 1994 to 2003 saw rapid development, with annual approvals trending upward amid fluctuations. Stimulated by early policies, enterprises actively applied, yielding an annual average of 227 approved products and peaking at 348 in 2002.

The decade from 2004 to 2014 was a period of fluctuation and adjustment. The average annual number of protected varieties granted decreased sharply to 69, representing a 70% decline. During this period, the stock of unprotected TCM preparations gradually diminished. At the same time, the State Food and Drug Administration issued the "Guiding Principles for the Protection of TCN Varieties" in 2009 [5]. These principles significantly raised the requirements for obtaining the protection of TCM varieties, clarifying that products applying for secondary protection must demonstrate clinical application advantages or better efficacy than similar varieties; In addition, varieties seeking renewal of protection were required to exhibit significant improvement in clinical, pharmacological and toxicological, and pharmaceutical aspects. These heightened requirements demonstrate that the "Regulations on the Protection of TCM Varieties" has achieved its initial legislative goal of regulating competition in TCM market and suppressing the low-quality competition among enterprises producing the same varieties.

From 2015 to 2024, approvals entered stability, with an extremely limited average annual number. The approval rate bottomed out at just 7 per year, only 3.2% of the total number in the first stage. This occurred because that TCM preparations to be

approved were limited and that policy changed in 2015. Therefore, with diminished innovation at the source, TCM protection approvals remained in the single digits.

2 Comparative analysis of the current Regulations on the Protection of TCM and the newly released draft for comments.

The core of the TCM variety protection system lies in the scope, methods, and levels of protection. Compared with the current regulations, the draft for public comments has made significant improvements to these core provisions.

2.1 Expansion of the protection scope

The draft for comments expands the protection scope by including Chinese herbal pieces and raw materials, achieving comprehensive coverage across the upstream and downstream industrial chains.

2.2 Adjustment of the protection level and term

The draft for comments adjusted the protection levels and periods. The current regulations classify protection into two levels: Level I and Level II. The protection period for Level I is 30 years, 20 years, and 10 years respectively, while the protection period for Level II is 7 years. However, the draft for public comments divides the protection of TCM varieties into special label protection and market exclusivity protection. Special label protection means that products that obtain the qualification for TCM variety protection in the future will have a protection label added to fixed positions on their instructions and packaging. Regarding market exclusivity protection, according to different product circumstances, a market exclusivity protection period of 5-10 years will be granted. The specific duration of exclusivity needs to be confirmed after the official release of the regulation. For products that obtain market exclusivity protection, drugs with the same name and formula will not be approved for marketing in the protection period. Meanwhile, the system of extending the protection period has been canceled, which means that varieties that obtain TCM variety protection must demonstrate continuous innovation. Only by virtue of new evidence or quality improvement can they obtain new protection qualifications again.

2.3 Renewal of the rights of certificate holders

The draft for comments grants affirmative rights to certificate holders, including prioritization in national essential medicine list, inclusion in treatment guidelines and clinical pathways, procurement and usage preference in medical institutions, access to the medical insurance list, and commercial insurance converage incentives.

3 Strategic repositioning of TCM enterprises for product protection qualification

After the implementation of the protection system for TCM varieties, many TCM enterprises seized the policy dividends and applied for protection for eligible products, cultivating big varieties and well-known brands. The main varieties include Fufang Danshen Dripping Pills (Tasly Group), Yunnan Baiyao (Yunnan Baiyao Group), Liu Shen Wan (Lei Yun Shang Pharmaceutical Industry), Jianwei Xiaoshi Pian (Jiangxi Jiangzhong Pharmaceutical), 999 Ganmao Ling Effervescent Granules (China Resources Sanjiu Medicine) and Fufang Ejiao Plasma (Shandong Don’e Group).

Following implementation of the new protection system for TCM varieties, certificate holders will gain expanded rights, and the market competitiveness of products with TCM variety protection certificates will be enhanced. This can

promote the business growth and brand value of TCM enterprises. At the same time, it will also inspire enterprises to increase R&D investment, promote technological innovation and continuous improvement, in order to cope with the increasingly fierce market competition.

According to the new policy direction revealed in the "Draft for Comments", TCM enterprises need to make strategic layouts so as to maximize the value brought by "TCM protection qualification" to enterprises.

3.1 Significance of "The exclusive logo of TCM protection" for TCM enterprises specializing in over-the-counter (OTC) products

3.1.1 Significance of the exclusive logo of TCM protection for the protected products

According to the literature reports in 2019 [7], there are 9,629 TCM products in China, most of which are non-exclusive products with multiple approval numbers. These products face intense competition in the market. For non-exclusive TCM products that meet the standards, especially over-the-counter (OTC) products, the title of "TCM Variety Protection" can provide recognition and support to manufacturers without hindering market competition. This approach not only encourages companies to continuously improve product quality and service levels but also enhances their brand image to better meet consumer needs.

From the marketing perspective, the significance of the exclusive logo protection for the protected products is as follows:

Firstly, the exclusive logo of TCM protection can enhance brand recognition. According to marketing theory, brand recognition refers to consumers' memory and recognition of the brand names, logos, symbols, etc. As a unique visual symbol, exclusive logo can quickly attract consumers' attention and improve brand recognition. Brand recognition helps to establish the market position of the brand and enhance brand loyalty [8]. For example, the ISO 9001 quality management system certification mark is widely used worldwide [9]. When enterprises and consumers see this sign, they know that the quality management of the product or service has reached international standards. Similarly, through its unique design and certification background, the exclusive logo of TCM protection can also significantly improve consumers' recognition of the protected TCM varieties.

Secondly, the exclusive logo of TCM protection has a strong credit guarantee effect and enhances consumer trust. Consumer trust is one of the important factors in making purchasing decisions. As a symbol of government certification, exclusive logo can enhance consumers' trust in products and reduce purchase risks. When buying products, consumers tend to give priority to those products with official certification, because these products have undergone strict inspection and certification, and their quality is more guaranteed. Exclusive logo can also convey a sense of trust to consumers, making them believe that the product complies with the relevant national standards and requirements. For example, CCC certification is China Compulsory Certification (CCC). CCC certification not only indicates that the product complies with the national standards of China but also significantly enhances the trust of consumers in choosing the product [10].

Finally, the exclusive logo of TCM protection can differentiate competitors and form a differential advantage with the same varieties, thereby improving market competitiveness. In the fiercely competitive market, differentiating competitors is the key to brand success. There are numerous TCM varieties in the market, and consumers are likely to feel confused when faced with products with similar functions and indications. As a unique visual symbol, the exclusive logo can help the protected

TCM varieties stand out from numerous competitive products, attracting consumers' attention. For example, China's "green food" logo has a high recognition level in the agricultural product market. Products with this logo often get higher sales in the market [11].

3.1.2 Significance of the exclusive logo for the improvement of quality standards

The application for the exclusive logo of TCM protection does not require exclusive production and is applicable to all patented TCM medicines that meet specific standards. These standards include sufficient evidence-based post-marketing studies, obvious clinical advantages, and significant improvement in product quality level by improving production technology and strengthening quality control.

For OTC TCM preparations, the feasibility of increasing evidence-based clinical research is relatively low. This is because ordinary consumers usually choose OTC drugs for treatment according to their own symptoms. With limited understanding of medical knowledge and evidence, they tend to stick to their habits or decisions even if provided with the evidence-based research results [12].

In this case, we can apply for the exclusive logo of TCM protection by improving the product quality standards, so as to form brand differentiation with other similar products in the market, and also enhance the trust of consumers, indirectly affect patients' choices, and help TCM enterprises stand out in the fierce market competition.

3.2 Significance of the rational integration of patents and TCM protection for pharmaceutical companies specializing in innovative TCM research and development (R&D)

3.2.1 National policies' efforts to promote the effective convergence of judicial protection and administrative protection for TCM

Patent protection belongs to the category of civil law, granting patentees the exclusive right for a certain period, and the rights holder can restrict or permit others to use their inventions and creations. In contrast, the protection of TCM varieties falls in the category of administrative law, which is implemented by the national drug supervision and administration department and has obvious public power attributes.

In fact, the "Opinions of the National Medical Products Administration on Promoting the Inheritance, Innovation and Development of Traditional Chinese Medicine" (2020) issued at the national level clearly points out that the protection of TCM varieties should be linked with patents [13]. It is said in the document, "The protection system of TCM varieties should be organically connected with the patent protection system and incorporated into the life-cycle registration management of TCM, playing its protective role on TCM innovative drugs, improved new drugs, ancient prescriptions of TCM compound preparations and other TCM varieties."

In addition, the "Opinions of the Supreme People's Court on Strengthening the Judicial Protection of TCM Intellectual Property Rights" released in 2022 also emphasizes this point, aiming to promote the connection between the protection of TCM varieties and patent protection through legal means, so as to comprehensively improve the judicial protection level of TCM intellectual property rights [14].

Under the guidance of national policies, this organic connection can make patent protection and the protection of TCM varieties work together at different stages and level to ensure the

comprehensive and effective protection of TCM innovations.

3.2.2 Requirement for the combination of patents and TCM variety protection from the lengthy R&D cycle

Because the R&D cycle of drugs is long and the effective protection period of core patents is short, enterprises often struggle to recover their R&D investment.

According to "China New Drug Registration Clinical Trial Progress Annual Report (2022)" [15], China's innovative drugs take an average of 7.6 years from clinical trial approval to market launch. Significant differences in the R&D time exist across drug types. Biological products have the shortest 4.6 years, followed by chemical drugs (6.9 years), while TCM require the longest timeframe (15 years). These data reflect the realities of China's innovative drug R&D, especially in the field of TCM, where the R&D process is more complex and time-consuming.

According to the "Patent Law", invention patents enjoy a 20-year protection period from the filing date. Consequently, when the core technology of a TCM product obtains patent protection in the early stages of R&D, it goes through a lengthy clinical research and approval process, and when the product is finally launched on the market, the patent protection period may almost come to an end.

Both the current regulations and their drafts for soliciting comments emphasize that TCM protection applies exclusively to commercialized products. Therefore, strong legal protection should be provided for new products through patent protection in the early stages of R&D. After the product is successfully launched on the market, the market exclusivity should be extended through the TCM variety protection system to further consolidate the competitive advantage of the product. This connection mechanism can not only motivate the continuous innovation of TCM enterprises but also effectively extend the commercial life cycle of the product, ensuring the reasonable return of long-term R&D investment.

3.2.3 Whole-life cycle management strategies for intellectual property protection of innovative drugs and TCM variety protection

3.2.3.1 Before product launch: comprehensive technology mining and patent layout

In the early stages of innovative drug R&D, pharmaceutical companies should conduct comprehensive technology mining to identify innovative core technology points and apply for patents as soon as possible. For innovative TCM, the core patents should focus on the formula compatibility and its specific uses. Applying for these core patents is just the starting point of patent layout. With the advancement of the R&D process, especially when the results of Phase III clinical trials are ideal, and the production process has is basically stable and the process parameters are clear, enterprises should promptly apply for invention patents for the preparation process and quality control methods. The application time of these follow-up patents needs to be optimized according to the expiration time of the core patents and the progress of the marketing application, so as to ensure the effective connection of patent protection.

It should be noted that the time interval between patent application and formal authorization is relatively long, which usually takes about 3 years [16]. The protection period of a patent is counted from the date of application, but the patentee can only formally exercise the patent right after the patent is authorized and announced. Therefore, when planning for patent applications, enterprises must fully

consider this time difference in order to maximize the effect of patent protection.

3.2.3.2 After product launch: application for TCM variety protection and continuous research

According to the current "Regulations on the Protection of Traditional Chinese Medicine (TCM) Varieties" and its guiding principles, after a product is launched on the market, TCM enterprises need to complete the relevant research work according to the requirements of the National Medical Products Administration (NMPA) when approving the product for marketing and issuing standards. The summary of these research works and related materials are important prerequisites for the application for the protection of TCM varieties. According to the current regulations, after the acceptance of an application for the protection of a TCM variety, the Drug Evaluation Center (CDE) will no longer accept applications for drugs with the same name and formula. Therefore, enterprises should apply for protection immediately after all the research required by the approval documents is completed and before the core patent expires, and obtain the acceptance notification letter for the protection of TCM varieties during this period.

After the product has successfully obtained the qualification for the protection of TCM varieties, TCM enterprise still needs to continue to invest in research, such as quality control and testing, optimization of extraction and preparation methods, and exploration of new application directions [17]. These research data not only facilitate patent layout, but also create favorable conditions for the renewal of protection.

In summary, obtaining the qualification for the protection of traditional TCM varieties is not the end, but a new starting point for enterprises to continuously innovate and protect intellectual property rights. A scientific and reasonable connection strategy between intellectual property and the protection of TCM varieties runs through the whole process of innovative drug R&D. Through early core patent applications, timely follow-up patent layout and post-launch protection of TCM varieties, TCM enterprises can effectively extend the protection period of products, enhance market competitiveness and promote the healthy development of the TCM industry.

4 Strategic opportunities and practical path prospects for TCM enterprises

With the deepening of the revision of the "Regulations on the Protection of TCM Varieties", TCM enterprises should keenly grasp the policy direction and regard the variety protection system as an important strategic fulcrum to drive innovative development. This institutional innovation not only conforms to the top-level design of the country to promote the inheritance and innovation of TCM, but also provides an institutional guarantee for enterprises to create differentiated competitive advantages. In particular, the optimization and upgrading of its evaluation dimensions is worthy of special study by the enterprise strategic departments.

In view of obtaining protection qualification for innovative drugs and improved new drugs, TCM enterprises needs to focus on strengthening the clinical value advantages and safety assurance capabilities. They should establish a comprehensive clinical evaluation system, systematically verifying the breakthrough performance of products in key indicators such as the certainty of curative effect, dimension of symptom improvement, and quality of life of patients. At the same time, they should improve the whole life cycle safety management mechanism from raw material traceability to post-marketing monitoring. In order to continue the protection of non-exclusive varieties, it is urgent to construct a dynamic evidence-based medicine

library, continuously carry out real-world research, and rely on modern detection technologies to establish a quality control standard system covering the entire industry chain.

The transformation of intelligent manufacturing has become a strategic choice to enhance the competitiveness of variety protection. TCM enterprises should actively promote the digital transformation of the entire production process. By introducing advanced technologies such as process analysis technology (PAT) and continuous manufacturing systems, intelligent regulation of process parameters and stable output of product quality can be achieved. The cultivation of this new quality productive force can not only meet the stringent requirements of the evaluation system for quality consistency but also enhance market competitiveness through cost reduction and efficiency increase.

In the dimension of internationalization, TCM enterprises should accelerate the docking with international botanical drug standards and establish a quality research system that conforms to international norms such as ICH and USP. They should also participate in international multi-center clinical trials, carry out research on the material benchmarks of classic prescriptions, and construct an evidence chain that can be recognized by the international academic community. This not only overcomes oversea market access barriers but also strategically elevates variety protection levels.

From the perspective of intellectual property strategy of TCM enterprises, the protection of TCM varieties has gone beyond the traditional administrative protection category and is evolving towards a composite intellectual property system. It is suggested that enterprises establish a collaborative mechanism between variety protection and patent layout, and form a multi-dimensional protection system of "patent + data protection + TCM variety protection" for core varieties. For non-exclusive varieties, taking the initiative to apply for exclusive protection marks can not only strengthen market recognition but also enhance product premium capability through authoritative endorsement.

Amid ongoing policy support, enterprises proactively securing TCM varieties protection will gain first-mover advantages in TCM modernization. Through the three-in-one systematic layout of deep clinical value mining, intelligent manufacturing upgrade, and international standard connection, TCM enterprises can establish innovative development models while advancing global health with China's solutions.

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