

Study on the Improvement of China's Pharmaceutical Patent Term Compensation System

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Abstract: The implementation of the pharmaceutical patent term compensation system can greatly stimulate the research and development enthusiasm of pharmaceutical enterprises, enhance the accessibility of medicines and promote the national health level. However, the system is still in the preliminary stage of implementation, and there are still a lot of inconsistencies with the real contradictions and the national situation. Through the study, it is found that the following problems exist in the implementation of China's pharmaceutical patent term compensation system: the details of the legislative provisions have not yet been perfected, the approval process cannot exclude the malicious opposition, the interests of creation and imitation are not yet balanced, and the opposition procedure is difficult to implement. Based on this, a systematic study of the legal framework and practice of pharmaceutical patent term compensation system in other countries is conducted, and corresponding solutions to the problems are proposed, i.e., improving the legislative framework and specific provisions, optimizing the examination and approval process and regulatory mechanism, balancing the incentives for innovation and the public interest, and establishing an opposition procedure to prevent abuse of rights, with a view to contributing to the improvement of the system.

Keywords: Pharmaceutical Patents; Patent Term Compensation; Pharmaceutical Research and Development; Pharmaceutical Accessibility.

1. Theoretical Basis of the Pharmaceutical Patent Term Compensation System

(1) Concepts and connotations of the pharmaceutical patent term compensation system

The pharmaceutical patent term compensation system is a system to compensate for the impairment of the patent validity period of a new drug due to clinical trials and strict administrative review during the process of marketing approval. The system was first created in the United States and has since been gradually adapted by Japan, Germany, Italy and other countries.

At present, there is no unified concept of pharmaceutical patent term compensation system, and scholars from different countries have put forward different opinions on the connotation of pharmaceutical patent term compensation system. Some scholars believe that because of the drugs as a special commodity, must be strictly approved to enter the market sales, and this leads to the impairment of the patent term can apply for the extension of the effective period of the patent, the system is called into the PTE system (Patent Term Extension). There are also scholars from the perspective of supplemental protection put forward the concept of drug patent term supplementation, that the drug patent term extension system refers to the system of supplemental protection in order to offset the reduction of patent validity caused by the process of clinical research, clinical trials and approval of drugs for specific drugs before they are listed on the market, the patent term protection system of the European Union is therefore called the supplemental protection certificate system. Therefore, the patent term protection system of the EU is called the supplementary protection certificate system. It can be found through the above viewpoints that the core of the pharmaceutical patent term compensation system is that the system was created to

compensate for the unreasonable reduction of the patent validity period and the compensation system.

(2) Positive significance of the pharmaceutical patent term compensation system

Pharmaceutical R&D is characterized by a long R&D cycle, high risk and high cost, and there is also the problem of reduced patent validity due to pharmaceutical R&D. These circumstances have made many pharmaceutical enterprises struggle and have difficulties in the early stage of R&D. Therefore, granting drug patentees a longer term of patent protection is likely to eliminate the difficulties of original research and development enterprises and further stimulate their R&D initiatives. In order to make up for the time spent on patent validity during the clinical trial and administrative approval stages, it is crucial to grant original research and development drug companies longer patent protection periods to ensure that they can make predictable profits, and in this way, the research and development of new drugs can be continuously promoted[1].

The implementation of the pharmaceutical patent term compensation system can attract more pharmaceutical enterprises to invest in the process of drug research and development, so as to develop original drugs needed by patients and scarce in the market. In addition, under the guidance of this system, it can also encourage generic drug enterprises to transform and upgrade, invest in the ranks of drug research and development, and improve the generic capacity and generic level in the process of drug research and development, so as to increase the competitiveness of the generic drug market, and further form the mutual competition with the original drug enterprises, which will effectively reduce the price of the original drug and improve the accessibility of the drug. In the United States, before the formal implementation of the drug patent term compensation system, patients mainly relied on generic drugs. After the implementation of the drug patent term extension system, many generic drug companies have shifted their focus to

originator drugs, which has also changed the situation of over-reliance on generic drugs. It can be seen that the implementation of the drug patent term extension system can promote drug accessibility, and also promote the transformation and upgrading of generic drug enterprises, and overall improve the international competitiveness of both originator drug enterprises and generic drug enterprises.

The implementation of the pharmaceutical patent term compensation system is of great significance in incentivizing pharmaceutical enterprises to carry out research and development of new drugs, greatly stimulating the research and development enthusiasm of pharmaceutical enterprises, and providing more high-quality and good drugs for the nation while comprehensively enhancing the strength of the country's research and development of new drugs. It can also promote the high-quality development of generic drugs, enhance the quality and accessibility of drugs, and promote national health.

On January 15, 2020, China and the U.S. reached the "China-U.S. First Stage Economic and Trade Agreement", which requires both sides to take reciprocal protection measures and establish a pharmaceutical patent term compensation system, which means that the establishment of the content of the pharmaceutical patent term compensation system in the legislation has become an international obligation of our country, which also shows that the establishment and implementation of the pharmaceutical patent term compensation system has a positive significance for the global pharmaceutical industry as well as for public health. This also shows that the establishment and implementation of a pharmaceutical patent term compensation system has positive significance for the global pharmaceutical industry and public health.

2. Problems with China's Pharmaceutical Patent Term Compensation System

(1) The details of the legislative provisions have not been perfected

There is still a long way to go to establish a patent term compensation system that suits China's national conditions and promotes the high-quality development of China's pharmaceutical industry. For example, regarding the calculation of patent term compensation for pharmaceutical products, the laws and policies that have been issued clearly compensate for the validity of patents, but the details remain to be improved. Although Article 85 of the Proposed Amendments to the Implementing Rules of the Patent Law (Draft for Public Comments) stipulates the calculation method of patent term compensation, the calculation method tends to favor the conservative model of the European Union, indicating that our country only fulfills the obligations stipulated in the China-U.S. Economic and Trade Agreements with the minimum requirements. The choice of the calculation method of the compensation term determines China's tendency and attitude towards innovative and generic drugs. Since 2019, new drugs independently developed by China have been approved for marketing in the U.S., indicating that China has moved from both original and generic to the stage of vigorously developing high-quality pharmaceuticals, and that only fulfilling the minimum obligations should not be China's current choice.

In addition, China's Patent Law defines the object of

application of the patent term compensation system as "patents for inventions related to new drugs that have been granted marketing licenses in China", but there is a lack of clear and specific provisions on what constitutes a "new drug"[2]. The Patent Law explicitly stipulates that only new drugs and their related patents can apply for extension of the patent term of pharmaceuticals; at the same time, according to the specific provisions of the invention patents related to new drugs, the new drugs are limited to four types of drugs, i.e., chemical drugs, biopharmaceuticals, innovative Chinese medicines, and new and improved Chinese medicines. This means that medical devices in China are not eligible to apply for pharmaceutical patent term compensation.

(2) Approval process does not preclude bad faith objections

At present, most countries in the world have adopted legislation to strictly regulate the clinical trials and administrative approval procedures before the marketing of new drugs. Such settings often lead to a reduction in the effective patent term of new drugs after they are marketed, and based on the high-risk, high-cost and long-cycle specificities of new drug research and development, it is generally difficult for pharmaceutical companies to obtain reasonable benefits and returns, which is not conducive to incentivizing them to carry out new drug research and development.

Article 85 of the Exposure Draft stipulates that "Where a unit or individual considers the granting of a compensatory term unreasonable, it may, from the date when the patent administration department under the State Council declares that the granting of compensation for the term is invalid, request that the decision on the compensatory term be declared invalid." This provision takes into account the impact of the term of patent protection on the public interest, grants the public the right to supervise, and encourages patentees to exercise their rights in accordance with the law, and encourages the patent administration department to cautiously grant a patent term that meets its conditions. However, this provision is ambiguous and poorly operationalized. The conditions for filing an opposition are highly subjective. From the perspective of textual interpretation, the expression "that the grant of the patent compensation period does not meet the conditions" can only be applied based on the subjective "think", does not exclude the possibility of malicious objection[3]. At the same time, the party's arbitrary application causes the administrative resources of the examination organization to be wasted, and is also extremely unfavorable to the healthy competition in the market. In addition, the legal consequences of invalidation have not been taken into account. The rights and obligations of the patentee during the compensation period are the same as those before the compensation, that is to say, the invalidation of the compensation decision means that the patent is granted only for the normal period of protection, and the rights and obligations during the compensation period cannot be obtained. If an objection is filed after the compensation period has begun, and only the patent administration department determines that the compensation decision is invalid, what should be done with the compensation period that has already ended, a question that is not clear in the current objection system.

(3) Creation of imitation benefits is not yet balanced

The main purpose of a pharmaceutical patent is to give the patentee a short-lived monopoly in return for disclosure of information about the invention by the patent applicant.

Because pharmaceuticals are cheap to produce and easy to hitchhike on, the pharmaceutical industry urgently needs a patent protection system to ensure that inventors can recover the cost of their inventions and benefit from them, so as to stimulate their motivation to innovate and research and ultimately realize innovation and development for the benefit of the whole society. However, over-protection of pharmaceutical patents, resulting in the creation and imitation can not reach a dynamic balance, will damage public health, and ultimately jeopardize the public interest.

As a result, there is currently an imbalance between originator and generic drug companies, and access to medicines remains a dilemma[4]. Promoting access to medicines is essentially a matter of balancing originator and generic medicines. As a necessity for maintaining health, drugs, based on their important role and research and development characteristics, must be provided with institutional safeguards for their research and development, so as to effectively promote the sustainable research and development of drugs. To a certain extent, the patent term compensation system can incentivize the research and development of original research drugs and ensure that patients have medicines to eat, but it can also delay the market launch of generic drugs due to the granting of a longer monopoly period to the patentee, resulting in the price of the original research drugs remaining at a high level for a long time and affecting the accessibility of medicines. By extending the patent term of drugs, more pharmaceutical companies can be guided to invest in research and development, for the same kind of drugs have more competitors, the original drug companies in order to compete for a larger market share, will adopt a certain degree of drug price reduction strategy, which to a certain extent, can also reduce the price of medicines, and to promote accessibility of medicines.

(4) Difficulty in implementing the objection procedure

According to Article 85 of the Patent Implementation Rules (Draft for Public Comments), if the patent administrative department under the State Council, based on the application of the pharmaceutical patentee, considers that the conditions for granting an extension of the term of the pharmaceutical patent have been met after examination, it shall make a timely announcement of the term of compensation and other related matters. The latter part of this provision stipulates the social supervision mechanism, which empowers all units or individuals to apply to the unit that made the decision on patent term compensation to declare the decision invalid if they believe that the content of the decision on patent term compensation made by the patent administrative department under the State Council does not comply with the statutory conditions for granting term compensation. The provisions of this article can not only urge the patentee of new drugs to exercise their rights correctly, but also ensure that the patent administrative department of the state council upholds a fair and rigorous attitude to make the decision to grant the patent term compensation, but does not have the possibility of practical operation.

The threshold for the public to initiate the public opposition procedure is too low, which is likely to encourage the wind of malicious opposition, and become a "weapon" for pharmaceutical companies to maliciously suppress their competitors, which is not conducive to the positive guiding function of the supervisory mechanism. According to the provisions of this article, any unit or individual who "thinks"

that the decision to grant a patent term compensation does not comply with the conditions of granting the patent law, can file an objection to the patent administrative department under the State Council. This means that at this time that will start the public objection procedure, the patent administrative department under the state council must immediately review the party's application. This practice of subjective judgment as the criterion for filing an objection may lead to some pharmaceutical enterprises to maliciously file an objection in order to suppress the listing of competitors' new drugs, which may not only harm the effective patent term of the R&D pharmaceutical enterprises in disguise, but also waste the resources of the State Council's administrative examination and approval, leading to a large number of new drug administrative examination and approval backlogs, and is not conducive to the improvement of the efficiency of drug examination and approval, which is obviously a departure from the original policy intent of China's current special drugs. This obviously deviates from the original intention of the current policy of fast approval and fast review of special drugs in China.

3. Legal Framework and Practice of Patent Term Compensation Systems for Pharmaceuticals in Other Countries

(1) U.S. Patent Term Compensation System for Pharmaceuticals

According to the provisions of the Hatch-Waxman Act of the United States, the patents applicable to the compensation of the patent term of pharmaceutical products include not only product patents, but also patents on the methods of use of products and patents on the methods of preparation of products, and these three types of patents can be applied for the extension of the patent term. It can be seen from the provisions of the bill, in the specific patent legislation, the United States uses the concept of drug superior "product" to summarize the types of eligible patents, which inadvertently expands the scope of eligible patents can apply for extension of drug patents. According to the provisions of the U.S. law, the products here can mainly include two types: the first type refers to pharmaceuticals, where pharmaceuticals mainly refer to new drugs, antibiotics or human biologics as well as veterinary new drugs or veterinary biologics; the second type mainly refers to the products other than

In addition to pharmaceuticals, medical devices, food additives or color additives are regulated by the US FFDA Act. Therefore, from the current US legislation, medical devices can apply for compensation for the term of drug patents in the same way as drugs.

Under the positive incentives of this system, U.S. domestic pharmaceutical companies have been motivated to conduct new drug research and development, which has brought unprecedented changes to the entire pharmaceutical market[5]. With the gradual maturation of the domestic pharmaceutical market, the United States, in order to safeguard the interests of domestic pharmaceutical enterprises in overseas markets, began to use international conventions and bilateral or multilateral trade agreements to promote the strong protection of intellectual property rights in the United States, and the patent term compensation system for pharmaceuticals belongs to the core of the strong protection of intellectual property rights in the important

content of the policy.

According to the requirements of the U.S. law, the pharmaceutical patentee must submit a complete and timely application for compensation for the term of the pharmaceutical patent within sixty days from the date of approval by the Food and Drug Administration. In terms of the influence generated during the implementation of the pharmaceutical patent term compensation system, since the implementation of the pharmaceutical patent term compensation system in the United States in 1984, the U.S. pharmaceutical industry has realized a gorgeous transformation from a large pharmaceutical country to a strong pharmaceutical country.

(2) Japan's pharmaceutical patent term compensation system

Japan's pharmaceutical patent term compensation system has the widest scope of application and the lowest threshold of applicability conditions, and can be applied for patent term compensation in respect of different pharmaceutical products of the same patent or different patents of the same pharmaceutical product.

The Japanese model has developed a very loose patent term compensation system based on the principle of extending the patent term compensation time as much as possible. It is reported that this did not allow Japan's local pharmaceutical innovation enterprises ushered in the development of the spring, but rather make foreign pharmaceutical companies to take the opportunity to seize the local innovative pharmaceutical enterprises originally occupied market share. Compared with the Japanese model, the EU only compensation for the approval of time-consuming calculation method to compensate for the original drug companies due to the approval of time-consuming shrinkage of the patent exclusivity period, and at the same time to limit the abuse of its rights to prevent the compensation period is too long on the impact of the generic drug companies, taking into account the original drug companies and generic drug companies between the balanced development of the drug industry can indeed maximize the protection of China's generic pharmaceutical industry-based pharmaceutical market.

(3) EU Patent Term Compensation System for Medicines

The EU requires that right holders applying for compensation for the term of a pharmaceutical patent must do so within six months from the date of authorization of the market launch of the pharmaceutical product or from the date of authorization of the basic patent, if they wish to obtain that right.

Compensation for the patent term of pharmaceutical products in the EU is mainly in the form of supplementary protection certificates. As of 2013, Supplementary Protection Certificates were in force in 29 countries, including Italy, Germany and the UK. Although the EU Supplementary Protection Certificate has reservations on whether medical devices can apply for extension of the patent protection period, the German court broke through the boundary of the protection of the Supplementary Protection Certificate system on the issue of whether to grant compensation for the patent term of a glass microsphere medical device, and held that the medical device combination product belongs to the pharmaceutical products with therapeutic purposes as stipulated in the SPC regulation, and can be granted a Supplementary Protection Certificate. According to the data of "2019 Top 100 Medical Device Companies List" published by QMED, a foreign third-party authoritative statistical

organization, the United States occupies 14 seats, Japan accounts for 2 seats, and the European Union accounts for a total of 4 seats in the list of the world's top TOP 20 medical devices. From the data, the United States has the strongest medical device R & D strength, and many of them are at the world's top level, which has a great relationship with the United States took the lead in the Hatch-Waxman Act expressly provides that medical devices can enjoy the extension of the patent term of drugs. By expanding the scope of application of pharmaceutical patent term compensation as a whole, it can effectively incentivize the research and development of drugs as well as encourage the enthusiasm of medical device research and development.

4. Improvement Path of China's Pharmaceutical Patent Linkage System

(1) Improving the legislative framework and specific provisions

Pharmaceutical patents compared to general patent research and development, research and development cycle is long and huge investment, China's patent law about the traditional protection of pharmaceutical patents is not conducive to highlighting the characteristics of incentives for research and development, which leads to China's pharmaceutical industry for a long time, the residents of the high burden of medical care, appropriate reference to foreign legislation, the introduction of pharmaceutical patents term compensation system can be a solution to the problem of a breakthrough. China is a large country of generic drugs, most of the national medicine is still relatively dependent on generic drugs, China's original research and development in the true sense of the number of drugs is still very small, if unauthorized reference to foreign legislation, will not only delay the generic drugs on the market, affecting the accessibility of medicines, but also due to the influx of foreign pharmaceutical market caused by the adverse effects of the domestic pharmaceutical enterprises.

The main focus of how to improve the compensation mechanism should be on clarifying the patent compensation standard. First of all, it is necessary to first determine the compulsory licensing patent of pharmaceutical patents on the issue of royalties, the TRIPS Agreement does not give a clear method of calculation and the exact amount, from a practical point of view, it is believed that each country can set the fee standard according to their own situation. Determine the compensation standard of royalties mainly consider two aspects: one is the economic value, that is, the pharmaceutical patent itself is expected to produce economic benefits, when the pharmaceutical patent system brings the income can not meet the people's expectations of profit, patent compensation standard should be based on the total amount of profit after compulsory licensing, delineate a specific amount. Compulsory licensing drug price reduction, inevitably accompanied by an increase in sales, so that the total profit is guaranteed, while drug sales are also mandatory licensing implementers voluntarily open, so as to ensure that the amount of profit openness and transparency. Secondly, it is a case-by-case situation, which is generally related to the economic base of the country. According to the experience of various countries, the royalties in most countries are between 4% and 6%. China can set the royalties within this range, compensate proportionally, and then analyze and sort out the

increase and increase in the degree of drug innovation and R&D investment of the original research and development enterprises, with the compulsory-licensed pharmaceutical enterprises paying the patentee within a specified period of time. The research of effective medicines for major public health crises is the most important task in relieving public health crises, in which the most prominent problem lies in the attitude of the implementation of the compulsory licensing system for pharmaceutical patents, to ensure that patentees do not need to worry about the protection of their rights without sufficient reasons. And in the post TRIPS era to appropriately raise the patentee compensation standards. This would provide an incentive for compulsory licensees to reinvest money and time in developing other innovative medicines, and these modalities could therefore be included in the compensation provisions for patentees as a means of creating a competitive domestic market.

(2) Optimizing the approval process and regulatory mechanism

Based on the strategy of Healthy China, China's pharmaceutical patent term compensation system should start from the main line of "needed, quality and affordable", and establish scientific term calculation methods and standards. Under the U.S. model, the compensation of experimental time and time-consuming approval is also beneficial to the construction of China's patent term compensation system. First of all, compensation for clinical trial time is more conducive to incentivizing drug innovation. The original drug companies in the clinical trial stage spend a lot of time, by the state to be compensated, which reduces the burden for the original drug companies, to prevent them to make the drug on the market as soon as possible and deliberately reduce the time of clinical trials. Clinical trials are the key to drug research and development, and sufficient clinical trial time is the basis for ensuring the quality of drug research and development, so compensating the time spent on clinical trials is in line with the strategic goal of "quality". In addition, compensating the time for non-diligence in review and approval is conducive to promoting better performance of the review and approval department. Since Article 42(2) of the Patent Law has clearly stipulated that "unreasonable delay caused by the applicant" shall not extend the patent term, the time of non-diligence in the review and approval shall refer to the time of non-diligence of the state organs responsible for the review and approval of the patent authorization and the approval of the marketing of the drug in the review and approval of the patent phase, i.e., to emphasize more on the government's responsibility. Article 96 of the Regulations for the Implementation of the Drug Administration Law of China stipulates the time limits for the registration and review of various types of drugs. Recently, the State Intellectual Property Office (SIPO) has asked the patent examination department to reduce the time for review and approval of pharmaceutical patents, in order to increase the initiative of government departments to promote the faster marketing of drugs. The shortened review and approval time is also a safeguard for clinical trial time, which is an adjustment made by the government to maximize the protection of adequate clinical trial time. Promoting the realization of drug accessibility does not only depend on the innovative research and development of enterprises, but also the macro-control role of the government should not be underestimated. Therefore, it is suggested that in the design of the specific rules of the patent term compensation system,

the calculation method of the U.S. patent term compensation can be used as the primary reference, and perhaps the patent term compensation system under the U.S. model has a more macroscopic and long-term vision than the calculation method of the European Union.

The current innovation market is dominated by foreign-funded pharmaceutical enterprises, and China's pharmaceutical innovation capacity is still relatively weak. The beneficiaries of the patent term compensation system are mainly enterprises with strong innovative capacity, so the possible impact of the system on China's local pharmaceutical enterprises should be taken into account when improving the patent term compensation system for medicines. In order to balance the development of the drug innovation market with the development of good and bad, the patent term compensation should also be appropriately limited.

(3) Balancing incentives for innovation with the public interest

In China's pharmaceutical enterprises R&D capabilities gradually enhanced, with the comprehensive consideration of foreign pharmaceutical enterprises to compete, the implementation of pharmaceutical patent term compensation system has a very important value and significance[6]. Pharmaceutical research and development is different from the general patent research and development characteristics, high research and development costs, high risk of research and development, research and development cycle is long, in the successful research and development of the market due to clinical trials and administrative supervision of the patent validity of the serious shrinkage; but as human beings to maintain the health of the body, enhance the body's immunity to the necessities, must be carried out in the research and development of new medicines. Based on this dilemma, the establishment of pharmaceutical patent term compensation system, to make up for the effective patent period of the pharmaceutical patentee's impairment, to ensure that it can get a predictable market returns, so as to incentivize drug research and development has an immediate and important role. This is the premise and guarantee for promoting the accessibility of drugs. The establishment of a pharmaceutical patent term compensation system can incentivize generic drug enterprises to invest in drug research and development, promote the transformation and upgrading of generic drug enterprises, improve the technical level of generic drugs, and avoid low-end homogenization and duplication of competition. Under the premise of establishing a pharmaceutical patent term compensation system, balanced development of innovative drugs and generic drugs should be taken into account, and a series of comprehensive supporting systems should be designed to realize the role of the pharmaceutical patent term compensation system in promoting the accessibility of drugs to the greatest extent possible, and realizing the balance between innovation and generic drugs.

(4) Establishment of an objection procedure to prevent abuse of rights

The essence of the public opposition procedure lies in the fact that since the decision on the extension of the patent term of pharmaceutical products is closely related to public health, all units and individuals are given the right to supervise it. However, the provisions of the proposed draft implementation rules of China's Patent Law on the public opposition procedure are not scientifically operable because the opposition threshold is too low, which can easily be reduced to a tool for pharmaceutical companies to maliciously

suppress their competitors, and it also wastes the resources of the administrative review and reduces the efficiency of the approval of the listing of drugs. At the same time, after the decision to extend the patent term of a drug is revoked, it is unclear how to characterize the legal consequences of a series of acts implemented during the patent extension period. Therefore, the following improvements can be made to the public objection procedure in the forthcoming implementation rules of the Patent Law. Since the patent administrative department of the state council to give pharmaceutical patentee term compensation decision announcement date, any unit or individual if there is prima facie evidence that the decision to give the patent term compensation does not comply with the statutory conditions, can be made to the patent administrative department of the state council of the patent term compensation decision to declare that the patent compensation decision does not comply with the provisions of the application. If, after examination, the patent administrative department under the State Council finds that the conditions for compensation under the Patent Law are indeed not met, it shall promptly inform the pharmaceutical patentee and the opposition applicant of the decision. After the decision on the compensation for the term of the pharmaceutical patent has been revoked, the patent term that has been extended shall be deemed not to have been extended from the beginning, and the legal consequences thereof shall be referred to as analogous to the provisions of Article 47 of the Patent Law. By further refining the criteria for filing opposition proceedings and clarifying the effect of relevant legal acts after the decision on patent term compensation has been revoked, it is possible to prevent the public opposition proceedings from becoming a piece of paper and deviating from the value orientation of public supervision.

5. Conclusion

The introduction of the pharmaceutical patent term compensation system has brought a new impetus to the development of China's pharmaceutical industry and

promoted the progress of China's intellectual property protection. The pharmaceutical patent term compensation system extends the protection period for new drug patents, the market exclusivity time of new drugs increases, and the original research drug companies can obtain more profits to support more R&D expenses for new drugs, forming a virtuous cycle of drug R&D and innovation. Although the pharmaceutical patent term compensation system is a foreign regulation, China did not blindly copy it when it was introduced, but took a series of measures based on the actual situation of China's pharmaceutical industry and the domestic reality, so its content is unique to China. As a new system, there will inevitably be shortcomings, and the relevant laws and regulations need to be clarified so that the system can truly meet China's basic national conditions and be put into practice, and can truly benefit the public and improve the level of China's pharmaceutical industry.

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