Study on Compulsory License System for Drug Patents in China

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ABSTRACT
In the wake of the COVID-19 epidemic, in order to solve the public health problems faced by the countries, it is urgent to improve China's compulsory license system for drug patents. By exploring the development of China's compulsory license system for drug patents and the practical experience of other countries, this paper analyzes the problems existing in China in this regard and puts forward some reasonable suggestions. Through case analysis, literature analysis and comparative analysis, the author obtains the reasons for the "zero implementation" of China's current drug patent compulsory license system and gives appropriate countermeasures. Under the current challenge of global public health security, there are contradictions between intellectual property rights and citizens' right to health, China needs to exercise the independent decision-making power conferred by relevant international treaties, reform the rigid starting mechanism of compulsory licensing of drug patents, and improve relevant laws based on protecting the legitimate rights and interests of patentees.

Keywords: *Compulsory license system, Drug patents, Public health.*

1. INTRODUCTION

Since 2019, the global outbreak of COVID-19 has taken place. All countries are working hard to develop new drugs for the disease while preventing and controlling the epidemic. Due to the long research and development (R&D) cycle, high investment cost and high failure rate of drugs, the pharmaceutical industry bears high risks. Therefore, the pharmaceutical patent system is extremely important in the pharmaceutical field. The system ensures the monopoly of drugs in a certain period so that drug patentees can obtain economic benefits during this period. This can not only ensure the recovery of the cost during the R&D period but also promote the R&D of new drugs to a certain extent. However, for some countries with underdeveloped economies and weak pharmaceutical R&D capacity, residents will not be guaranteed the right to life and health because they can't afford high prices for drugs. After the production of the new vaccine for COVID-19, the problem of uneven distribution of the vaccine in various regions has gradually become prominent. In the context of the conflict between intellectual property rights and public health rights, the drug patent compulsory licensing system is a good choice to solve the problem. However, China has not practiced the compulsory license system of drug patents before, so this paper hopes to improve the progress of China's compulsory license system of drug patents by analyzing relevant cases in developing and developed countries combining with the problems of China's relevant legislation, to prepare for the future and ensure the health and safety of citizens. China needs to clarify the policy orientation, improve the implementation links and establish a drug quality supervision and post relief mechanism to ensure that the drug patent compulsory license system plays a role, protect intellectual property rights and realize citizens' right to health.

2. COMPULSORY LICENSE SYSTEM FOR DRUG PATENTS

The compulsory license for drug patents is a system in which a country carries out the compulsory license for drugs with legitimate reasons without the permission or authorization of the drug patentee so that the applicant can obtain the right to produce and use the drug patents that do not belong to him and makes reasonable

compensation to the original patentee [1]. Under the outbreak of COVID-19, the conflict between drug patents and human health rights is becoming more and more serious. If there is no suitable way to solve this problem, it will be harmful to public health.

According to the current legislation and practice of various countries, the compulsory license of drug patents can be roughly divided into three categories: the compulsory license to limit the abuse of patent rights, the compulsory license to protect public health interests and the compulsory license of dependent patents[2]. The compulsory license prohibiting the abuse of drug patent rights refers to that the drug patentee holds the drug patent right for a long time without implementing or making full use of it, and does not make a reasonable explanation, which makes it difficult to meet the demand for drugs in the market and hinders scientific and technological innovation. At this time, the country should maintain free competition and ensure market order through the compulsory license of relieving monopoly behavior. There are two kinds of compulsory licenses to protect public health interests: compulsory licenses based on special circumstances such as national emergencies and compulsory licenses to protect public health. Article 31 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS) stipulates that when a contracting party is in a state of national emergency, the applicant for a compulsory license may not need to go through the process of "negotiating with the patentee within a reasonable period and being refused permission for implementation", but shall still notify the drug patentee within the shortest time after obtaining the compulsory license. When there are serious problems in public health and citizens' lives are seriously threatened, the state can grant the applicant a compulsory license for drug patents to reduce the price of patented drugs and improve the accessibility of drugs, so as to ensure the safety of public health. However, it can not be used for commercial use. Compulsory licensing of dependent patents means that the implementation of the latter patent depends on the implementation of the former patent, and compared with the former patent, the latter patent is a major scientific and technological progress that has an important impact on economic and social development[3]. If the former patentee does not allow the latter patentee to use the technology, the state may grant a compulsory license for the implementation of the former patented drug, so as to ensure the smooth progress of the latter patented technology.

The patent system is essentially an encouragement of innovative knowledge, aiming at the happiness of all mankind. The compulsory license system of drug patents is the basis for selection when intellectual property rights are in contradiction with health human rights. Its function is to restrict and restrict the exercise of drug patent rights to a certain extent, protect the accessibility of drugs and public interests, give consideration to the purpose of stimulating innovation and protecting the interests of patentees, and finally achieve the balance between public health and patent rights [4].

3. COMPULSORY LICENSE SYSTEM FOR DRUG PATENTS IN CHINA

3.1 Legislative Status of Compulsory License System for Drug Patents in China

Since the promulgation of the first patent law in 1984, with society paying more and more attention to public health and safety, the compulsory license of drug patents in China has gradually developed into a relatively complete system from the initial individual provisions. So far, the relevant contents of China's drug patent compulsory license system have been stipulated in the patent law and various administrative laws and regulations, but generally speaking, there are still many deficiencies in various legislative systems. In the first patent law, drug patents are not regarded as the object of patent rights[5]. In 1992, China and the United States reached a memorandum of understanding on the protection of intellectual property rights. According to the memorandum, China also revised the patent law for the first time, increased compulsory license in the public interest, and included drugs in the scope of patent protection. In 2000, China joined the WTO and revised the patent law for the second time. In order to be in line with the TRIPS Agreement, China has revised the compulsory licensing system of drug patents in accordance with Article 31 of the TRIPS Agreement, and imposed stricter restrictions on the implementation conditions of compulsory license. Article 50 of the TRIPS Agreement further clarifies the reasons for the issuance of "dependent patents" and requires them to have "significant technological progress of significant economic value"[6]. When the patent law was revised for the third time in 2008, the articles of the law on the compulsory license

system of drug patents were increased from 8 to 11, which were further improved in content and more stringent in application conditions. This amendment added Article 48 compulsory license for antitrust relief and Article 50 compulsory license for the export of patented drugs[6]. The patent law was revised for the fourth time in 2020. On the original basis, articles 50 to 52 on patent opening license were added, and Chapter VI "compulsory license for patent exploitation" was changed to "special license for patent exploitation". It can be seen that the repeated amendments to the patent law and the promulgation of relevant laws and regulations reflect China's emphasis on drug patents and the trend of connecting with international standards. Since the 20th century, China has joined the Paris Convention and signed the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, which has promoted the protection of intellectual property rights.

3.2 Legislative Issues of Compulsory License System for Drug Patents in China

Since the implementation of the patent law in 1984, the number of the practice of China's drug patent compulsory license system has been zero. Guangzhou Baiyunshan "Tamiflu" case is the first attempt at compulsory licensing of drug patents. In 2009, China's influenza A (H1N1) was very serious, and the specific drug Tamiflu produced by Roche for the treatment of avian influenza was effective. At that time, two companies in China were authorized to produce Tamiflu. Guangzhou Baiyunshan Pharmaceutical Company also applied to Roche pharmaceutical for the production authorization of Tamiflu but failed. In the same year, the company successfully developed a generic drug of Tamiflu, and the price was lower. It applied for generic drug registration to the State Food and Drug Administration, hoping to carry out bioequivalence experiments in advance using compulsory license, but failed. At that time, influenza A was in full compliance with Article 49 of China's patent law in 2008, and the drugs for the treatment of the disease had been authorized in China, and Baiyunshan Pharmaceutical Company also had the ability to produce the drug, but the compulsory license for drug patents was still unimplemented. Firstly, the mortality rate of influenza A was not high and can be controlled. Secondly, the implementation of the compulsory license system of drug patents may be detrimental to international trade. In fact, at that time, there was no precedent for the implementation of compulsory licensing of drug patents in China, and the construction of the intellectual property system was not perfect, so it was difficult to implement this system.

So far, after the fourth revision of the patent law, there are still some problems in China's drug patent compulsory license system. The legislation of the drug patent compulsory license system is scattered. The provisions on the compulsory license system of drug patents are mainly distributed in the patent law, the detailed rules for the implementation of the patent law and the measures for the compulsory license of patent implementation, with many levels, which is not conducive to understanding and application [7]. The relevant provisions on the compulsory license system of drug patents are not perfect. In terms of the reasons for applying for a compulsory license, China did not combine its national conditions but directly used several situations in the TRIPS Agreement. It is difficult to start the implementation of the system without expanding the scope of application causes. In addition, the relevant provisions have too many restrictions on the applicant, and the concept of some terms is vague. The application procedure is too cumbersome. If the country encounters a public health crisis and the trial cycle is too long, it is likely to lead to an irreparable situation [8]. So far, in a series of laws and regulations issued by China, there are too many regulatory subjects, which will lead to the problem of overlapping or missing responsibilities. More importantly, China currently lacks a special supervision department for drugs produced due to patent compulsory licenses. For example, if the patentee is lazy in implementation, it will damage his rights. If the compulsory license exceeds the specified scope, it may affect the implementation of compulsory license of drug patents and the protection of public health in China.

At the same time, China only stipulates the implementation conditions of drug patent compulsory license but does not make relevant provisions on the maintenance and relief of the patentee, which may also lead to the abuse of the rights by the compulsory licensor, which will too damage the interests of the patentee, attack the enthusiasm of drug R&D enterprises, and is not conducive to the development of China's drug industry.

4. ANALYSIS OF THE LEGISLATION OF COMPULSORY LICENSE FOR DRUG PATENTS IN VARIOUS COUNTRIES

4.1 Compulsory License for Drug Patents in Developed Countries

As the vast majority of large pharmaceutical enterprises are located in developed countries, developed countries have always emphasized the protection of drug patents to ensure their own economic interests. When there is a serious public health crisis in their country, developed countries prefer indirect ways such as negotiation to obtain the needed drugs[9]. Typical cases include the United States and Canada.

4.1.1 Compulsory License for Drug Patents in America

The United States is a powerful pharmaceutical country. For the interests of its pharmaceutical enterprises, the United States pays more attention to the monopoly of drug patents and does not establish regulations on the compulsory license of drug patents. However, when facing a serious public health crisis, the United States often adopts the way of negotiation to ensure its drug demand. The anthrax epidemic broke out in the United States in 2001. Ciprofloxacin, a drug for treating anthrax produced by Bayer company of Germany, was the only drug approved by the U.S. government, but the patent period of this drug was not over at that time. The American people can't afford the cost of $700 for a course of treatment, so they strongly recommend that the state use the drug patent compulsory licensing system for Ciprofloxacin. However, in order to prevent developing countries from following the example and creating a passive situation in the future, the United States negotiated with Bayer and asked them to reduce drug prices, otherwise it would start the compulsory license system of drug patents[10]. Finally, Bayer had to reduce the price of the drug.

From this case, people can see that even developed countries need compulsory licenses of drug patents to ensure public health and safety. Even if the United States did not recognize this system, it also used this system to reduce the price of drugs. The US government has also repeatedly used this method to solve the crisis of drug shortage, which can not only protect citizens' right to health but also protect competition and realize antitrust.

4.1.2 Compulsory License for Drug Patents in Canada

Different from the United States, Canada has stipulated the compulsory licensing system in the patent law and has been constantly revised in the past century. From 1923 to 1969, Canada's patent law first stipulated the compulsory licensing system of drug patents, but the applicable object was limited to the active ingredients in drugs produced in Canada, so the number of cases passed was very small. From 1969 to 1992, Canada amended the patent law to allow the compulsory license system of imported drugs, and the Canadian people also enjoyed the lowest price of drugs. From 1992 to 2005, Canada promulgated act c-91, announcing the complete abolition of the compulsory licensing system of drug patents and strengthening the protection of drug patents. In 2005, Canada revised the patent law and the food and drug law again and added "using patents for international humanitarian purposes to solve public health problems" to the patent law [11]. This system is designed to help to develop and underdeveloped countries obtain needed drugs. In 2007, Rwanda successfully obtained the compulsory license to import TriAvir for the treatment of AIDS.

Canada has been exploring the compulsory licensing of drug patents and revising its patent law concerning the provisions of international treaties. At present, it can help other countries obtain the required drugs while protecting drug patents.

4.2 Compulsory License for Drug Patents in Developing Countries

Compared with developed countries, developing countries and underdeveloped countries use drug patent compulsory license systems more often. Because of the low economic level and weak scientific research capacity, these countries usually cannot develop drugs by themselves, and ordinary people cannot afford the cost of imported drugs. To protect public health and safety, these countries need to use the drug patent compulsory license system to introduce low-cost drugs, such as India and Thailand.

4.2.1 Compulsory License for Drug Patents in India

It was not until 2005 that India brought drug patents into the protection scope of patent law according to the TRIPS Agreement, which

accelerated the development of the generic pharmaceutical industry. The compulsory license of drug patents in India is divided into three categories: General patent compulsory license, special patent compulsory license and export patent compulsory license [12].

In 2012, India used the drug patent compulsory license system for the first time to obtain the production right of Sorafenib for the treatment of advanced renal cancer and liver cancer in India [13]. Bayer applied for and authorized the patent of Sorafenib in India in 2008, but most people can't afford it because of the high cost. So NATCO, an Indian generic drug company, applied to Bayer for a generic drug license, but after being rejected, it applied to the Patent Administration for a compulsory drug patent license. Bayer applied for reconsideration to Indian Intellectual Property Appeal Board(IPAB) but was rejected. IPAB said that if Bayer's petition was approved, the interests of public health would be damaged. It is the responsibility of the patentee to supply drugs at a reasonable price to meet the medical needs of the public. Bayer appealed to the Supreme Court of India and still got the same answer. As a result, India's first case of compulsory licensing of drug patents was successful, reducing the price of drugs and ensuring the accessibility of drugs to the public.

4.2.2 Compulsory License for Drug Patents in Thailand

In order to fight against the spread of AIDS in Thailand, the government of Thailand first used the compulsory license for drug patents in 2006. It granted the right of the Thailand government medical organization to imitate the production of efavirenz of Merck, thus reducing the cost of AIDS treatment by 50%. In January 2007, the government of Thailand approved another two compulsory licenses for the treatment of AIDS drugs, but the move also made Thailand's Government under various political and economic pressures. In order to ease relations with the U.S. government, the Thai government announced in 2008 that it would terminate the compulsory license of four cancer drugs, but revoked the decision against the opposition of its people and charities [14].

After experiencing many difficulties, Thailand has successfully implemented the compulsory license of drug patents, reduced drug prices, protected citizens' health rights and interests, provided an experience for other developing countries, and enhanced their confidence in implementing the compulsory license of drug patents.

5. SUGGESTIONS ON PERFECTING THE COMPULSORY LICENSE SYSTEM FOR DRUG PATENTS IN CHINA

5.1 Clarifying the Policy Orientation of Drug Patent Compulsory License System

From the previous cases, it can be seen that the policy positioning of drug patent compulsory license in developed countries and developing countries is completely different. For China, it needs to formulate its own compulsory license system according to relevant international treaties in combination with its actual situation. With China's increasing emphasis on intellectual property rights, drug patents have been protected through systems such as drug patent links, an extension of protection period and drug experimental data protection. At the same time, the accessibility of drugs is guaranteed through the medical insurance system. Given the current situation in China, it is suggested to use the direct implementation system and negotiation to make use of the compulsory license system of drug patents. When public health and safety are seriously threatened or the price of drugs for special diseases is too high, the direct implementation of the drug patent compulsory license system can be adopted. The negotiation method is mainly used to promote the patentee to agree to reduce the price of drugs, which can effectively avoid international disputes and protect the interests of the patentee to a great extent.

5.2 Improving the Implementation Phase of the Compulsory License for Drug Patents

5.2.1 Clarifying the Applicable Conditions of the Compulsory License for Drug Patents

In China's patent law, it is stipulated that the compulsory license system of drug patents is applicable to solve national emergencies or for the public interest, as well as the manufacture and export of compulsory licensed patented drugs for the purpose of public health. However, the terms "public health" and "public interest" are not clearly defined. It is suggested to explain the vague

definitions in the law. In addition to infectious diseases that are seriously harmful to public health, it is also recommended that drugs with noninfectious diseases with high incidence rate, high mortality rate and high drug prices should be included in the list of medical insurance so that the number of start-up permits for drug patents will be reduced.

5.2.2 Simplifying the Compulsory License Procedure for Drug Patents

The public health crisis has the characteristics of urgency, and the compulsory license procedure used to alleviate the crisis should be simplified as much as possible. After the State Intellectual Property Office makes a compulsory license decision, it shall take immediate effect to avoid delaying medication treatment. Relevant state departments should establish a fast track for the priority examination and approval of the compulsory license for drug patents in emergencies and designate appropriate units to quickly start the compulsory license for drug patents. For the patentee, simplifying the procedure can save time and cost, while for the public, it can quickly alleviate the health crisis and protect the right to life and health.

5.2.3 Expanding the Scope of Applicants for the Compulsory License of Drug Patents

One of the reasons why China's compulsory license for drug patents has not been implemented so far is that the applicant's subject qualification is too strict. The patent law stipulates that the applicant for a compulsory license must be a unit or individual that meets the conditions for implementation. In case of the public health crisis, the applicant can only be the State Intellectual Property Office. This requirement is too hard for most Chinese enterprises and individuals. In Canada, Britain and other developed countries, the applicant can be anyone. Referring to the system of applicants and initiators in India, a developing country(See "Table 1"[12]), it can be seen that India limits the initiators to the Indian government only in the case of special patent compulsory license, while in other cases, the initiators and applicants can be any person, which is conducive to increasing the number of applications for drug patent compulsory license.

Table 1. Scope of compulsory license grant in India

	General patent compulsory license	Special patent compulsory license	Imported patent compulsory license
Promoter	Any stakeholders	Central government of India	Countries that lack or do not address public health issues
Applicant	Any stakeholders	Any stakeholders	Any stakeholders

5.2.4 Determining the Compensation Standard for Compulsory License for Drug Patents

Although the compulsory license of drug patents is for public welfare, it does damage the interests of the patentee. Without reasonable compensation, it may reduce the enthusiasm of enterprises and individuals to develop new drugs. The United Nations Development Programme (UNDP) recommended 4% of sales compensation. If the drug has a specific therapeutic value, the cost will increase by 2%. If the R&D process takes up a lot of public resources, the cost will decrease by 2%. However, the specific amount should be determined in combination with the actual situation of the country [15].

5.3 Establishing a Compulsory License Drug Quality Supervision and Relief Mechanism

The purpose of the drug patent compulsory license system is to protect the health rights and interests of the public. If the implementer of compulsory license produces drugs at low cost and sells them at high prices to earn profits, or produces unqualified drugs, it is against the original intention of the drug patent compulsory license system. The state should set up a special department to supervise the sales and quality of drugs with compulsory licenses. If there are patients with adverse reactions, they should report to the relevant departments in time and treat the patients in time [16].

6. CONCLUSION

The compulsory license system of drug patents pursues the balance between intellectual property rights and public interests. So far, China has not implemented the compulsory license system of drug patents, which reflects the imperfections of relevant laws and regulations and the inappropriate environment. Under the influence of COVID-19, China hopes to make improvements so that the compulsory license system for drug patents will really play a role.

To improve the compulsory license system for drug patents, we not only need to modify laws and regulations according to the national situation but also create an environment suitable for the implementation of the system in China. China's ability to develop new drugs is weak. The government needs to increase financial support in this regard to effectively improve China's ability of independent research and development. Moreover, China should also cultivate the sense of social responsibility of pharmaceutical enterprises and encourage them to contribute to the protection of public health and safety. Then, we should strengthen international cooperation. China should learn from developed countries the technical conditions for drug production, communicate and learn more, and improve its pharmaceutical level.

It is hoped that China can modify and improve the compulsory license system of drug patents and make full use of this system. Whether it is enforced or negotiated by using this system, the purpose of allowing the people of the country to pay for the drugs they need at a low price can be achieved. With the continuous improvement of China's scientific and technological innovation ability, the drug patent licensing system will be successfully implemented and the public interests of the people will be better protected.

The study on other countries that have implemented the compulsory license system for drug patents could be more in this paper. Analyzing how they deal with the problems of drug supervision and patient relief after the implementation of the compulsory license system can be used as a reference for China's system construction. After China begin to implement the compulsory license system for drug patents, the sales, quality supervision and patient medication of drugs after listing are hoped to be studied more.

AUTHORS' CONTRIBUTIONS

This paper is independently completed by Kaiyue Zhou.

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