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Research on Patent Compulsory License System based on Intellectual Property Protection

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Abstract. One of the important mechanisms of the patent system is to promote technological innovation and progress by protecting intellectual property rights. With the continuous strengthening of intellectual property protection worldwide, the conditions and scope of intellectual property license granting are becoming increasingly stringent. Compulsory licensing of patents is a restrictive right that constrains the monopoly of the patent owned by the patentee. Insufficient protection of the rights and interests of patent holders can lead to poor implementation of the compulsory patent licensing system, reduced innovation momentum of patent holders, and intensified technology trade friction, which in turn affects the implementation and normal functioning of the system. In recent years, public health problems, led by COVID-19, have become increasingly serious in various countries, which has seriously affected the health of people around the world. Faced with the severe public health situation, the compulsory licensing system for pharmaceutical patents achieves an effective dynamic balance between private patent rights and public health rights. This article takes pharmaceutical patents as an example to analyze the current situation of China's compulsory licensing system for pharmaceutical patents and provide relevant suggestions.

Keywords: Intellectual Property Protection; Patents; Compulsory Licensing System.

1. Introduction

Since the beginning of the 21st century, due to factors such as the surge in population and cross-border mobility, infectious diseases have occurred frequently around the world [1]. In recent years, public health crises have emerged one after another. Diseases such as COVID-19, HIV and cancer have been endangering human life and health [2]. To effectively address the current public health issues, we must strengthen the supply of drugs and improve their accessibility.

Law, as the most powerful weapon for safeguarding the vital interests of the people, is one of the important means to address public health issues [3]. Faced with the severe public health situation, the conflict between drug patent protection and public health interests is becoming increasingly acute. In extremely special circumstances, in order to ensure the needs of public health, it is possible to use the patent technology of drugs to third parties without the consent of the drug patent holder through national enforcement, in order to balance the protection of patent rights with the need to ensure public health [4]. Intellectual property has exclusivity and exclusivity. In a sense, intellectual property is a legitimate monopoly. The significance of intellectual property system is to stimulate human innovative thinking and ability through exclusive protection of intellectual achievements of intellectual property owners, drive the overall development of the social economy, and improve the overall welfare of society [5]. Among the various legal systems in various countries, the law that safeguards public health is a very important content regardless of which country. The compulsory licensing system for pharmaceutical patents, as a highly public welfare system, is an important member of relevant laws. According to the existing Chinese patent system, if a drug patent is granted, even if its compound structure is disclosed, the drug cannot be arbitrarily copied without the consent of the patent holder. The compulsory licensing system is a key measure to improve drug accessibility and balance the legitimate interests of drug patent holders, following the principles of "priority protection of legal interests" and "balance of interests" [6]. The relationship between the compulsory licensing system for drug patents and public health is closely and inseparable. The establishment and application of drug patents are related to the real life of the people of a country. When considering the design of a country's compulsory licensing system for drug patents, it is not only necessary to

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align with the institutional standards of the international community, but also to consider the domestic situation, based on the country's economic development level and situation, Establish a system that is practical and feasible based on the actual situation of the country [7].

Compulsory licensing of patents is an important institutional design for balancing rights, which itself does not lead to unfairness. It is only whether the rights and interests of the patentee under compulsory licensing can be fairly protected that is the cause of institutional disputes, which directly affects the effectiveness of the system. Studying the compulsory licensing system for pharmaceutical patents is beneficial for legal improvement and the improvement of the intellectual property system. At the same time, a sound system can provide theoretical support for practice, thereby promoting the specific implementation of the system and promoting the construction of the rule of law in China.

2. The Current Situation and Dilemma of China's Drug Patent Licensing System

2.1. Current Situation

Table 1. Five types of compulsory licensing for Chinese pharmaceutical patents

Stage type		Unimplemented	Monopolistic behavior	Emergency or public interest	Dependent patent	Export for public health purposes
Start	Starting main body	Units or individuals with implementation conditions	Units or individuals with implementation conditions	National Knowledge Bureau	The latter patentee can apply for cross licensing after the latter patentee applies for it	Units with implementation conditions
Review decision	Market supply scope	Domestic	Unlimited	Domestic	Domestic	Countries and regions specified in international treaties to which China has joined
Termination		Termination situation	The compulsory license period has expired; Patent invalidity or expiration of protection period; The reason disappears and the patent holder applies; Withdrawal of application			
Relief		Compulsory licensing decisions	Proceeding			

China has been adjusting the compulsory licensing system for drug patents since 1984, and the basic system of this system has been basically formed. However, in China, there have been no cases of this system being implemented so far. Article 57 of the Chinese Patent Law stipulates that the patentee may receive a reasonable compulsory patent licensing fee or handle the fee in accordance with relevant international treaties to which China is a party. If consultation fails, the patent administration department of the State Council shall make a ruling [8]. However, the definition of "reasonable" for "reasonable usage fees" and how to make rulings if negotiations fail are not clear. Patent compulsory licensing is an effective means to address the abuse of patent rights in unconventional situations. However, patent compulsory licensing is also a challenge to the patent system and cannot be frequently used as a routine means. Otherwise, it will shake the foundation of the patent system and pose a greater threat to drug accessibility. From the perspective of compulsory licensing, there are two types of compulsory licensing: monopolistic compulsory licensing and compulsory licensing for

exporting drugs for public health purposes, and regulations are made for the scope and conditions of applicants, as well as the determination process of compulsory licensing fees, to gradually complete and standardize China's compulsory licensing system for pharmaceutical patents. The framework of China's compulsory licensing system for pharmaceutical patents is gradually improving. According to the current Patent Law and relevant normative documents, the five types of compulsory licensing for pharmaceutical patents in China are shown in Table 1.

2.2. Dilemma

The current laws and regulations on compulsory licensing of drug patents in China do not have a thorough understanding of the TRIPs agreement. Internationally, it is generally recommended to abide by the agreement in the TRIPS agreement. Although many WTO members have their own freedom to start compulsory patent licensing, in the case of serious domestic health events, such as COVID-19, they can use public life as a reason to start compulsory patent licensing [9]. China's drug policy orientation is unclear, failing to take into account the supply and demand contradiction between the low productivity of patented drugs and the large amount of therapeutic drugs required in the event of a major epidemic. It does not focus solely on improving the affordability of drugs from the perspective of addressing their accessibility. The implementation of compulsory licensing systems for drug patents in different types of countries often results in differential treatment by developed countries such as the United States. In addition to significant differences in the implementation attitudes and methods of the compulsory licensing system for drug patents among countries, from a macro perspective, the different positioning of the system between developed and developing countries also leads to different choices in specific application areas. Table 2 shows the purposes of compulsory licensing for drug patents in different countries. With the aging population, cancer and cardiovascular diseases have gradually become serious factors affecting China's health level. As a middle-income and high-income country with steadily improving international status and scientific research level, China can withstand a certain degree of international pressure and has the ability to produce generic drugs. Therefore, it is fully capable of using the compulsory drug patent licensing system when necessary [10].

Table 2. Usage of compulsory license for drug patents in different countries

Country		Infectious disease	Non-communicable disease
Developing country	India		Tumor Cancer
	Brazil	HIV/AIDS; Hepatitis B	
	Thailand	HIV/AIDS	Cardiovascular; Tumor Cancer
	Russia	Bacterial infection virus	
Developed country	America	Anthrax	
	Germany	HIV/AIDS	
	Italy	Bacterial infection virus	Neurology department

3. Strategies for Improving China's Compulsory License System for Pharmaceutical Patents

3.1. Improving Legislative Capacity

Developing countries should flexibly apply and formulate mandatory licensing conditions that are conducive to their own development within the scope set by the TRIPs agreement based on their own conditions. Based on China's public health level, economic and social development level, and the international trade environment it faces, it is necessary to clarify China's policy positioning of "primarily addressing the availability of patented drugs under major epidemic situations, supplemented by addressing the affordability of drugs for major infectious diseases". In order to prevent the abuse of patent monopoly rights, it is necessary to provide a more flexible compulsory

licensing system. Integrate the institutional norms for compulsory licensing of pharmaceutical patents, avoid duplication of provisions, and achieve the accuracy of legal provisions. At present, China's attitude towards compulsory licensing is too cautious. It should flexibly use TRIPs clauses, add "government use" clauses, and give the government more freedom and usage rights.

The Chinese Patent Law should stipulate that anyone can apply for a compulsory license, remove the restriction that applicants must meet the implementation conditions, and stipulate that anyone can apply for a compulsory license. Expanding the application subject and relaxing the subject qualification restrictions not only comply with international common practices, but also meet the objective current situation of China's drug accessibility needs. Based on China's current comprehensive national strength and development stage, it is necessary to establish a market-oriented orientation for fair patent royalty protection to stimulate innovation. For compulsory license application cases involving patent monopoly, the applicant is granted the right to apply for examination from the antitrust law enforcement agency. The antitrust law enforcement agency defines the market related to patent technology, analyzes the competition situation in the upstream and downstream markets of the disputed patent products, and makes a comprehensive judgment on factors such as whether the right holder holds a dominant position in the market.

3.2. Building a Scientifically Sound Institutional System

The standard for setting license fees not only needs to consider the legitimate rights and interests of the patent holder and the degree of voluntariness in negotiating authorization, but also takes into account the applicant's economic payment ability, the normal profitable profits brought by compulsory patent licensing, and the social benefits generated. Before the implementation of the compulsory license, a reasonable compensation for the rights holder should also be determined, and a proposal should be issued by the antitrust law enforcement agency. Both the formulation of compensation fees and compulsory licensing measures should be transparent, and the government should disclose compensation fees and expenses to society. This not only prevents the breeding of corruption, but also facilitates the supervision of patent holders and society. Establish various functional departments for implementing compulsory licensing of drug patents, establish good communication channels, so that each department can quickly coordinate and handle problems in the event of a crisis.

The core essence of implementing compulsory licensing for drug patents lies in safeguarding the public's health rights and interests. It is necessary to establish a quality supervision mechanism that covers the entire drug life cycle. Not only should pharmaceutical companies be strictly supervised in the research and development and production processes, but also through the establishment of patient tracking and damage relief mechanisms, the recovery of patients after taking drugs should be tracked on a large scale, and feedback on discomfort symptoms of patients should be strengthened. If necessary, special procedures for damage relief should be used to timely ensure the safety of public life and health. Chinese patent laws and regulations have guaranteed the right to know of patent rights in compulsory licensing through procedures such as consultation, hearing, and notification. In the future, the construction of early warning procedures should also be strengthened. Prevent generic drugs from entering the market or even illegally exporting, truly ensuring that all generic drugs are effective, effectively treating every patient who needs treatment, and alleviating public health crises. At the same time, we will work together with the customs department to vigorously crack down on the illegal export of counterfeit drugs and protect the rights of patent holders as much as possible.

4. Conclusion

Compulsory licensing of intellectual property rights is developed in order to maintain the reasonable use of intellectual property rights and meet the needs of social public interests. The patent law, as an intellectual property law, serves economic development, while the legislative purpose of drug regulations is to safeguard public interests and promote public health. They all belong to

administrative regulations, and the maintenance of public interests is their common purpose. However, their starting points are the public's property rights and health rights, respectively. The establishment of this system contains values such as priority protection of legal interests, balance of interests, and prohibition of abuse of rights. It plays an important role in safeguarding the public's right to life and health, regulating conflicts of interests among all parties, and preventing patent holders from abusing their rights. Public health and safety have always been a highly valued part of China, but currently China is still a developing country with weak drug research and innovation capabilities. This has led to a small number of patented drugs in China, high drug prices, and many patients being unable to afford high medical expenses and giving up treatment. The compulsory licensing of drug patents has its particularity, which is the conflict between the private nature of drug patents and their social attributes. We need to flexibly apply the relevant theories of administrative law and patent law to propose suggestions for improving the system, in order to obtain a scientifically feasible system to safeguard public interests.

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