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Should China Implement Compulsory Drug Patent Licenses? - From the Perspective of COVID-19

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Abstract: Although China has already issued laws and regulations on compulsory licensing of pharmaceutical patents, it has not yet implemented specific practices. After the outbreak of "COVID-19", realistic needs have made it urgent for China to implement compulsory drug patent licensing. Therefore, this study will be based on China's national conditions, combined with China's laws and regulations on the compulsory licensing of pharmaceutical patents, and compare specific practices in other countries. Through qualitative analysis, it's clear that China implements compulsory pharmaceutical patent licensing in three aspects: domestic system, international level, and government responsibility. To analyze the feasibility of China's drug patent compulsory licensing system and provide suggestions.

Keywords: COVID-19; Compulsory Licensing; Pharmaceutical Patents

1. Introduction

In this part, I will briefly introduce the historical background, legal background and international background of China's implementation of compulsory drug patent licensing, and point out that the entry point for the research subject is the "COVID-19" sweeping the world. In addition, I will raise three key research issues related to the compulsory licensing of pharmaceutical patents.

Although the compulsory licensing system of pharmaceutical patents is stipulated by law in China, there is no specific practice. Therefore, in terms of the difficulties it faces, discussions should be conducted from the perspective of before and after the implementation of compulsory licensing of pharmaceutical patents, system defects and international perspectives. When a foreign country develops a vaccine, can China compulsorily license it for use, or can the vaccine be popularized in China after China has developed a vaccine? The purpose of this research is to analyze this issue in order to protect the public interest.

The theme of this research is "COVID-19" as an entry point to discuss whether China should implement compulsory drug patent licensing. The goal is to provide suggestions on the difficulties China faces in implementing this system in light of legal provisions and international experience.

Here I want to raise three research questions:

1. Analyze the difficulties in implementing the compulsory licensing of pharmaceutical patents from a domestic perspective.

2. From an international perspective, can China learn from the experience of other countries?

3. Analyze the responsibilities of the Chinese government, including the necessity of the use of compulsory drug licenses and the government's responsibilities when unpredictable consequences occur after the issuance of compulsory license.

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2. Literature review

In this part, I will summarize the views of Chinese scholars on the compulsory licensing of pharmaceutical patents, analyze the legislative process of China's compulsory licensing of pharmaceutical patents, analyze the legislator's intentions and the background of the times, and finally form personal view on the current status and licensing of compulsory licensing of pharmaceutical patents in China.

The significance of writing this section is to clarify the domestic historical background and international legal background of China's implementation of compulsory drug patent licensing. The scope of the review is the journal literature and case analysis related to the compulsory licensing of pharmaceutical patents, and the basic content is the development process of the compulsory licensing of pharmaceutical patents in China and the unsolved problems in the system.

From the perspective of the development process, I have summarized the three important nodes in the development of China's drug patent compulsory licensing: In 1992, China's "Patent Law" was amended for the first time, and drugs were included in the scope of patent protection, and the conditions for implementing compulsory licensing were "the state of emergency" Or "in exceptional circumstances" or "for the purpose of public interest"; after the SARS outbreak in 2003, China included "the emergence and epidemic of infectious diseases leading to public health crises" as a "national emergency"; in 2008, China served internationally Friendly mutual assistance has increased the application of compulsory patent licenses to help other countries solve public health problems. Until now, when China or the member states of international treaties that China is a party to encounter a public health crisis, the State Intellectual Property Office can issue compulsory licenses for patented drugs in accordance with the Patent Law. In the development of compulsory drug patent licensing under the multilateral trading system, most countries still have not implemented compulsory drug patent licensing. Developing countries such as Angola, Lesotho, and Tanzania use more compulsory patent licensing than developed countries. Meanwhile, India's Proprietary drugs are produced at will under the government's permission.

From a legislative point of view, China has perfected the supporting system for drug administrative approval. The newly revised "Drug Administration Law" stipulates the accelerated approval procedures for urgently needed drugs in public health[1], and the "Administrative Measures on Drug Registration" also issued regulations, "Special approval for drugs urgently needed for prevention and treatment of public health emergencies, and for major emergencies Vaccines urgently needed in public health events can be subject to conditional approval after assessing that the benefits outweigh the risks."

In summary, although China has solved the legislative issue, it is still in a vacuum in the practice of compulsory licensing of pharmaceutical patents. I think its system needs to be improved. The first thing to do is to solve the problem of unclear provisions in domestic legislation "for public health purposes" and expand the scope of compulsory patent licensing. Second, it is necessary to clarify the government's responsibilities and reduce the possibility of canceling the compulsory patent license after the government and the drug manufacturer reach an agreement to reduce the price of the drug. Finally, in the international community, we will strive for the interests of developing countries led by China, and implement compulsory licenses for drugs that cannot be independently researched and developed by the country but are needed by the public to meet the health needs of the people, and to increase the availability and affordability of drugs.

3. Methodology

In this part, I will explain the subject analysis method and content analysis method that I used in my research, and point out the limitation of the research method.

The purpose of this study is to analyze the practical difficulties faced by the implementation of the compulsory licensing of pharmaceutical patents in Chinese legal provisions and propose countermeasures. Therefore, typical examples are used to explore the feasibility of the Chinese government's implementation of compulsory drug patent licensing by the "theme analysis method", and the "content analysis method" is used to analyze India's positive attitude towards compulsory drug licensing. The above research methods have the advantages of flexibility and maneuverability. The direction can be adjusted in time, without a lot of data research,

and the cost is very low.

Through the above research methods, I have analyzed two compulsory licensing procedures for Chinese drug patents, namely, initiation based on authority and initiation based on application. For "COVID-19" drugs, it is more feasible to implement compulsory licensing of drug patents under government authority. So we need to focus on government authority. At the same time, the proliferation of generic drugs in India is actually the result of the government's enforcement of compulsory licenses ex officio. So in terms of content analysis, we can focus on comparing the differences between Chinese law and Indian law. And in China, the laws and regulations for compulsory licensing of pharmaceutical patents in China include: Article 20 of Chapter 2 of the Vaccine Administration Law of the People's Republic of China[2] and Article 49 of the Patent Law[3], which stipulate that the benefits outweigh the risks after evaluation, or for the purpose of public benefit, you can apply for a compulsory license for drug patents. It can be seen that China has sufficient legal support for the implementation of the compulsory license of drug patents.

Finally, the limitation of academic research is hard to avoid. In my opinion, the limitation of this research is because China is still in a blank in the practice of compulsory licensing of pharmaceutical patents. Therefore, the research lacks specific examples for analysis and does not conform to the research method of "positivism".

4. Results

In this part, I will summarize the difficulties China faces in implementing compulsory drug patent licensing from various angles.

Domestically, China has never implemented the compulsory licensing of pharmaceutical patents before, lacks sufficient experience, and faces multiple difficulties: the domestic legislation provides for "for public purposes" is not clear; China's implementation of compulsory licensing of pharmaceutical patents is complex; The Chinese government's implementation of compulsory licenses will do more harm than good. It will undermine the innovation mechanism and exacerbate Sino-US trade frictions. Therefore, China has not yet implemented compulsory licenses. In addition, since China does not yet have the ability to produce generic drugs, and for national interests, it cannot imitate India to produce generic drugs. Finally, most domestic scholars believe that the problems faced by China in implementing compulsory drug patent licensing should be attributed to the domestic system.

5. Discussion

In this part, I will theoretically analyze how China should overcome the difficulties of implementing compulsory drug patents, and discuss the responsibilities of the Chinese government, pharmaceutical companies, and public hospitals in the process of implementing compulsory drug patents, that is, legal risks.

In theory, first of all, I think that the scope of "for public purposes" stipulated in China's "Patent Law" should be broadened to include the "COVID-19" vaccine. Secondly, I would like to supplement the previous views on the difficulty of China's implementation of compulsory drug patent licensing, and increase the international influencing factors—that is, the influence of Western countries with patent discourse power led by the United States has prevented the Chinese government from successfully implementing compulsory drug patent licensing. Therefore, China The government should use compulsory licensing instead of negotiating drug price reductions under the permission of international treaties.

As far as the actual impact is concerned, I think it is necessary to discuss whether China can learn from the implementation experience of other countries. As far as India's experience is concerned, China does not have the conditions for mass production of generic drugs, and in consideration of national interests, it cannot be applied. As far as the experience of using sympathetic drugs in the United States is concerned, China can appropriately learn from it and expand the license scope of drugs that are still in clinical trials to ease the pressure of compulsory drug patent licensing.

In addition, I do not support the view that the Chinese government's implementation of compulsory licenses does more harm than good, because in the case of "COVID-19", once vaccines are developed without compulsory licenses for drug patents, the government has to bear serious dereliction of duty that harms national health responsibility. Although there are opinions that the compulsory licensing system itself and its lower compensatory nature will weaken the innovation enthusiasm

of pharmaceutical companies, violate the purpose of the patent system, and even cause international disputes and trade frictions. However, China's current demand for "COVID-19" drugs is very urgent, which is fully in line with the national emergency, and the interests of the patentee should be subordinate to the interests of the country and the nation. Therefore, the benefits of curbing "COVID-19" outweigh the risks, and the concept of compulsory licensing should be changed.

Finally, I would like to raise a question that cannot be answered at present: Imagine that China has implemented a mandatory license for the "COVID-19" vaccine, but if there are unpredictable consequences, such as death of the injected population, should the government and relevant implementing agencies bear the responsibility of compulsory license? Can a pharmaceutical company that can participate in the production of vaccines after enjoying the benefits of a compulsory license be exempted from liability for defects in the vaccines it produces? In other words, since the side effects of vaccines and other drugs are inevitable, the government can implement compulsory licenses for vaccine patents and encourage pharmaceutical companies to produce vaccines in large quantities. At the same time, public hospitals can force people to sign a letter of responsibility before obtaining vaccines, so that they can be injected. Will the risk of the "COVID-19" vaccine be transferred to the vaccinators? This is because if the Chinese government implements compulsory licensing of pharmaceutical patents, risks will be inevitable, and the size of the risk is also an important factor in its consideration of whether to implement compulsory licensing. This point needs to be taken seriously in the future.

6. Conclusion

In this part, I will summarize the results of the study from three perspectives: point out the analysis of the difficulties faced by China in implementing the compulsory licensing of pharmaceutical patents; summarize the supporting measures that need to be introduced after the implementation of compulsory licensing in China; and whether China should implement compulsory licensing Answer the question-China must implement compulsory licensing of drug patents.

1. First of all, the difficulties China faces in implementing the compulsory licensing of pharmaceutical patents should be viewed from both the domestic cautious attitude and the international environment.

2. On the basis of reforming the domestic approval system, China should strengthen restrictions on compulsory licenses to promote its implementation. For example, after the disappearance of "COVID-19", vaccine patents need to return to the patentee. And strengthen the protection of the rights and interests of drug patent holders, ensure that the implementation rights of drug patents are not monopolized, and strictly regulate the scope of use. Secondly, China should speak out for developing countries, advocate international mutual assistance, and actively create the basic conditions for the implementation of compulsory drug patent licensing.

3. In short, I think it is necessary for China to implement compulsory licensing of pharmaceutical patents, and it will be of reference significance to other countries. China should implement compulsory licensing of pharmaceutical patents.

References

1. China's "Drug Administration Law": "For the treatment of severely life-threatening diseases without effective treatment and drugs that are urgently needed in public health, the clinical trials of drugs that have data that have shown the efficacy and can predict their clinical value can be approved with conditions."
2. Article 20 of Chapter 2 of the Vaccine Administration Law of the People's Republic of China: "For vaccines that are urgently needed in response to major public health emergencies or other vaccines that are urgently needed by the health authority of the State Council, the benefits outweigh the risks after evaluation, the State Council's Drug Administration Departments may conditionally approve vaccine registration applications. In the event of a particularly major public health emergency or other emergencies that seriously threaten public health, the health authority of the State Council will make recommendations for emergency use of vaccines based on the needs of the prevention and control of infectious diseases. It can be used urgently within a certain range and time limit after the management organization organizes the argumentation.
3. Article 49 of the Patent Law: "When a state of emergency or emergency occurs in the country, or for the purpose of public interest, the Patent Administration Department of the State Council may grant a compulsory license for the exploitation of invention or utility model patents."