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International Technology Transfer Perspective: A Study on China's Compulsory Licensing System for Pharmaceutical Patents

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Abstract: Ensuring the supply of medicines is extremely important during major public health crises. Implementing compulsory licensing of pharmaceutical patents is a means to guarantee an adequate and effective supply of medicines. Although China's current compulsory licensing system for pharmaceutical patents has clear legal provisions, there are many issues. To ensure the effective implementation of the system, it is necessary to relax the qualifications of the applicants, add new objects of compulsory licensing, clarify the reasons for application, and explore more efficient application procedures.

Keywords: Compulsory licensing; Public health crisis; Pharmaceutical patents; TRIPS agreement

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1. Introduction

The frequent occurrence of global public health safety events poses a significant threat to human health and has caused major economic losses to the world. In these events, the high cost of medicines due to pharmaceutical patents is particularly prominent, especially in developing countries and regions. The general public cannot afford expensive medicine costs, which makes it difficult for moderately or severely ill patients to obtain reasonably priced and effective medicines. This exacerbates the difficulty of resolving public health crises. In this situation, the introduction of the compulsory licensing system for pharmaceutical patents can find a balance between individual interests and public interests. The system allows the government to authorize third parties to produce or sell patented medicines without the consent of the patent holder under specific circumstances to meet public health needs. This approach can promote the completion of the medicine transaction process in a timely manner to meet the urgent demand for special patented medicines without infringing on patent rights through the intervention of public institutions.

2. China's compulsory licensing system for pharmaceutical patents

2.1. Concept

The compulsory licensing system for patents refers to a legal mechanism where administrative departments such as the National Intellectual Property Administration allow third parties to produce, sell, or import patented products or use patented methods without the authorization of the patent holder under specific conditions. The patent holder then receives a certain remuneration from the licensee. This system aims to balance the interests of patent holders and social public interests, especially in emergencies or public health crises, to ensure the accessibility of key technologies or medicines [1].

2.2. Conditions for use

This usually occurs when the patent owner refuses to authorize, or when an agreement cannot be reached within a certain period. In such cases, third parties can apply to the patent management authorities for compulsory licensing. In some emergencies or public health crises, the government may also grant compulsory licensing for the sake of public interest. In any case, the party obtaining compulsory licensing must pay a certain usage fee to the patent owner. If the two parties cannot reach an agreement on the fee, it will be determined by relevant national departments. In special situations, such as when public health is seriously threatened, the state may issue a compulsory license for pharmaceutical patents, allowing third parties to produce generic drugs with the same effect as patented medicines to safeguard public health rights and interests [2].

2.3. Value foundation

2.3.1. Preventing the abuse of pharmaceutical patent rights

The TRIPS agreement regards intellectual property as a private right, allowing pharmaceutical patent holders to reasonably regulate market supply and pricing to recoup their investments and achieve economic benefits. However, some large enterprises use pharmaceutical patents to strengthen their market monopoly positions, restrict competition, and thus destroy the free order of market competition. To limit the unrestricted use of pharmaceutical patent rights and break the malicious monopoly situation, the compulsory licensing system for pharmaceutical patents plays a key role.

2.3.2. Alleviating public health crises and safeguarding basic human rights

The right to health is considered a basic human right and holds an extremely important position. In recent years, various infectious diseases have caused serious epidemics worldwide, posing significant public health challenges to countries. As emphasized in the Doha Declaration, the protection of intellectual property should not hinder a country from taking necessary measures to safeguard public health but should aim to promote member states in ensuring public health, especially ensuring that people can obtain essential medicines [3].

3. Deficiencies in China's compulsory licensing system for pharmaceutical patents

3.1. Strict application subjects

China's patent law clearly limits the qualifications of applicants for compulsory licensing of pharmaceutical patents, usually only allowing government agencies to apply. For other types of compulsory licensing, applicants are usually "entities or individuals with the conditions to implement" or "persons with direct interests." Although the patent law allows individuals to apply for compulsory licensing to prevent the abuse of

patent rights, when the requirement of "having the conditions to implement" is added, the number of individuals who can meet this condition is greatly reduced.

3.2. Narrow scope of application

According to the provisions of the Patent Law Implementation Regulations, the objects of compulsory licensing are limited to "patented products or products directly obtained by the patented method." This means that only patented medicines that have been granted patent rights can become the objects of compulsory licensing, while those pharmaceutical technology solutions that are in the patent application stage and have not yet obtained patent rights are not included. At the same time, China's patent law does not have clear legal provisions on whether compulsory licensing applies to pharmaceutical patents that have not undergone clinical trials.

3.3. Ambiguous reasons for licensing

Article 54 of the Patent Law mentions that compulsory licensing can be granted in cases of "emergency", "extraordinary circumstances", or "for public interest", but the definitions of these terms are not clear and lack specific standards. This results in administrative organs having a large degree of discretion in actual operations, which may affect the effective implementation of the system [4]. In addition, the application conditions for compulsory licensing are stipulated in an enumerative manner, without including a flexible clause for "other circumstances" to cope with various unforeseen emergencies or special situations. This may lead to a lack of adaptability and flexibility of the law when facing unexpected emergencies or special situations [5].

4. Paths to improve China's compulsory licensing system for pharmaceutical patents

4.1. Appropriately relaxing the qualification restrictions on application subjects

For government entities, it is suggested to clarify in the law that the National Health Commission can jointly assess and propose suggestions for compulsory licensing with the National Medical Products Administration and other relevant departments to maintain public health. The scope and application procedures of "relevant departments of the State Council" should be determined, and a public supervision mechanism should be established to ensure that the government actively fulfills its duties. For social entities, it is recommended to relax the qualification of "entities or individuals with the conditions to implement" to "entities or individuals with the possibility to implement." There is no need to require them to have actually met the conditions for implementation, as long as they have the potential to implement the patented technology subject to compulsory licensing. Finally, it is suggested to add "entities or individuals with the possibility to implement" as applicants in the patent law. Through these modifications, the flexibility and effectiveness of the compulsory licensing system for pharmaceutical patents can be improved, better serving public health needs.

4.2. Adding new objects of compulsory licensing

It is suggested to expand the definition of "medicines" in the patent law to include pharmaceutical patent applications and patented medicines that have not undergone clinical trials. Including ungranted pharmaceutical patent applications in the objects of compulsory licensing is essentially a preliminary recognition of their patent rights. This allows them to be treated as non-patented medicines when rejected while following the relevant rights and obligations stipulated in the patent law when authorized [6].

4.3. Clarifying the reasons for the application of compulsory licensing for pharmaceutical patents

Firstly, the wording of Article 54 of the Patent Law should be adjusted to "in cases where the country faces emergencies, extraordinary circumstances, and other situations affecting public interest" to clearly express the hierarchy and connection between these concepts. Secondly, more specific definitions or standards should be provided for key terms such as "public interest", "emergency", and "extraordinary circumstances." The circumstances in which "public interest" is damaged can be specifically defined, such as when medicine prices are far beyond the public's ability to bear or when market demand is not met. Furthermore, it should be clear which diseases constitute "emergencies" or "extraordinary circumstances." Combining the actual situation in China, infectious diseases with high incidence, strong contagiousness, and significant health hazards, as well as chronic non-communicable diseases, should be included in the scope of application for compulsory licensing of pharmaceutical patents, and specific explanations should be provided in relevant regulations. Finally, a catch-all clause such as "other circumstances that meet the reasonable needs of the public" should be added to the patent law as a supplementary reason for compulsory licensing. This will more flexibly cope with various emergencies and better safeguard public health.

5. Conclusion

In the post-pandemic era, people have a deeper understanding of the importance of public health rights to personal safety. Especially in the face of major public health emergencies, the institutional support provided by the law is extremely important for everyone. International legal practices have fully proven the importance of the compulsory licensing system for pharmaceutical patents in ensuring the availability of medicines and protecting public health. As a system arrangement that balances patent rights and public health rights, the purpose of compulsory licensing for pharmaceutical patents is not only to improve the availability of patented medicines but also a reflection of the pursuit of legal values.

Disclosure statement

The authors declare no conflict of interest.

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