Announcement of the Conflict and Coordination of China's Drug Patent Compulsory Licensing System under the Health Crisis

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Abstract. Public health is currently a significant issue in growing China and even on a worldwide scale. SARS, H1N1, H7N9 avian influenza, and the recent outbreak of coronary pneumonia are just a few of the significant health and safety disasters that have significantly jeopardized public health in our nation in the first two decades of the twenty-first century. One of the most challenging concerns affecting Chinese people's ability to support themselves has been the public health problem.

This paper examines the current state of the difficulties in implementing the compulsory licensing system for pharmaceuticals in China, compares the provisions and implementation of the system in developed and developing nations, such as India and Brazil, and reviews pertinent literature to highlight the deficiencies of the compulsory licensing system for pharmaceuticals in China and offer suggestions for improvement.

Keywords: Public Health, compulsory licensing, pharmaceutical patents, public health prevention and control, pharmaceutical accessibility

1 Introduction

The recent outbreak of neonic pneumonia has made it clear that nations from all over the world are spending a lot of money and researchers to research and develop vaccines and effective drugs, and that many developing nations are spending a significant amount of money and resources to purchase such drugs. As a result, the long-dormant patent compulsory licensing system for drugs is once again the subject of research by academics from different countries. The Statute of Inventors, which was adopted in Venice in 1474, contains the following language: "The government may decide ex officio to use the inventor's device and apparatus in social management activities, but it shall be operated by patentee. This was the birthplace of the first modern patent law in the world. Although China has legal provisions for the compulsory licensing of pharmaceutical patents, there is still no implementation. The compulsory licensing system for pharmaceuticals, as a means of regulating public health, is of great significance. After the introduction of this law, the development of the Venice trade was promoted.

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2 Literature review

2.1 Development of the patent system

In industrialized foreign nations, compulsory licensing rules for patents were established early and have matured. The German Patent Law, which was established in 1877, allows for the cancellation of patent rights. The patent authority may directly revoke the patentee's rights if they use their patent in an unreasonable manner or refuse to allow others to use it for the benefit of the public interest. This precedent helped create the modern European patent compulsory licensing system, which was later adopted by many other nations around the world. The 1994-enacted TRIPS Agreement's Article 31 states that, in cases of public interest, in response to significant public health events, national security, etc., patented pharmaceutical technology may be used or allowed to be used without the patentee's consent in exchange for a fee that is paid to the patentee. Article 31 of the Agreement states that, in exchange for payment of a fee to the patent owner, the patent holder may use or permit others to utilize the patented pharmaceutical technology without the patent owner's agreement.

Since there haven't been any applications or decisions regarding compulsory licensing of pharmaceutical patents since China's Patent Law was passed, the majority of domestic scholars have primarily focused on the pertinent provisions of the TRIPS Agreement in conjunction with China's unique provisions and national requirements. The majority of studies can only remain at the theoretical level because there are no specific situations to investigate.

2.2 Features of the compulsory licensing system for pharmaceutical patents

The compulsory licensing system for pharmaceutical patents has some special characteristics that set it apart from other patent systems since it is a constraining measure for the patentee and a helpful one for the licensee: First, the licensing mechanism for pharmaceutical patents is mandatory rather than optional. First, the licensing system for pharmaceutical patents that is required but not voluntary. When the state or the government implements compulsory licensing for pharmaceutical patents, it often does so in cases of emergency or grave emergency where there are no better alternatives available at the moment. Second, pharmaceutical patent licensing requirements are statutory in

nature. The intellectual property law and other laws clearly outline the requirements and particular processes for the implementation of the pharmaceutical patent compulsory licensing system. These requirements must be satisfied in order for the system to be implemented, and these requirements cannot be granted arbitrarily. Thirdly, the extent and timing of the mandatory licensing system for pharmaceutical patents are unpredictable, and the mandatory license should only be issued in response to a specific emergency circumstance and for a specified reason. There is no longer a requirement for a mandatory license.

2.3 Analysis based on consumer demand in the pharmaceutical market

China is the most populous nation on earth, making it impossible to ignore the demand for pharmaceuticals there. People have become increasingly concerned about their physical and mental health since China's reform and opening up, along with the trend of economic development, the improvement of people's living standards, and the implementation of the health insurance system, and the value of a healthy body and mind is growing. Fast-paced lifestyles, high levels of stress, and an ageing population are also contributing to an increase in health issues. From the standpoint of medical costs, it is important to note that medical costs in China are rising annually, reaching 3.5 trillion RMB in 2014 and exceeding 2,500 RMB per person. Both numbers are 3.5 times greater than in 20069, and while there is still a difference when compared to industrialized nations, it has significantly closed. Additionally, consumers have a rigid demand for drugs, and this demand will only grow as China's population base grows, the population ages, the incidence of chronic diseases rises, people's living standards rise, the concept of medical services changes, and the reach of health insurance coverage broadens. This demand will be especially pronounced for drugs with strong therapeutic effects. Therefore, the national standard drug manufacturing industry should, on the one hand, encourage the development of high-quality drugs for independent research and development investment projects in the drug manufacturing industry and, on the other hand, promote the development of the pharmaceutical industry in a positive direction, under the specific guidance of the significant demand for drugs and specific needs. Second, royalties should be strictly monitored and drug prices should be regulated.

2.4 Patent conflicts for pharmaceutical companies

While the opponent of a drug patent criticizes the difficulty of affordability caused by high drug prices and charges that the drug patentee or the dominant country has a "ruthless" and "cruel" monopoly, the patentee determines that its monopoly status is legal based on the patent system and actively defends this status. The monopoly position is vigorously defended by the patent holder, who has concluded that it is legal under the patent system. The conflict between the right to patent and the right to life and health in the pharmaceutical industry actually led to the questioning of the patent system itself, with one side arguing that the system allows for the existence of monopoly status and results in pharmaceutical companies manipulating drug prices for high profits at the expense of the public interest, and the other side arguing that the system is justified for

the purpose of encouraging innovation and protecting the fruits of knowledge. New drugs created at tremendous price and effort will be easily replicated without the protection of the patent system, making it impossible for the developers to recoup their expenses and turn a profit. The patent system gives the developer exclusive rights to make money and reinvest it in further drug development, creating a positive feedback loop. It is unsustainable to pursue economic gains at the expense of the public's right to life and health since such exclusive rights will certainly result in a considerable increase in the cost of patented pharmaceuticals, which have the particular responsibility of treating diseases and defending the right to health. The conflict between the right to life and health and the patent rights of pharmaceutical firms arises as a result of patients who require medicines to regain their health and save their lives but are unable to access them.

3 Discussion

First, public health encompasses both the general well-being of the population as well as the health of the individual. Second, promoting public health is a group effort that depends on the social fabric of society as a whole. Because of the current trend of global integration, the public health crisis has become a challenge shared by the entire international community. Third, the state is the primary subject of the right to public health. The state is responsible for ensuring the realization of the people' right to health, and it must take proactive measures to do so through a variety of channels. In other words, the protection of public health is extremely important since it closely reflects and links to the public interest of society.

Since China has highly rigors regulations regarding medication applications, our legal system does not take into account China's streamlined process for approving generic drugs. Although generic applicants are permitted to submit applications for generic pharmaceuticals within two years of the patent period's expiration, it is challenging to complete the three clinical trials required by our law, which prevents many generic drugs from going on the market by that time. Many generic medications are therefore unable to be sold by then.

Regardless of the mechanism used for compulsory licensing of pharmaceutical patents, the following features are seen when examining the practices in various countries: First, countries approach the implementation of compulsory licensing of pharmaceutical patents with caution. According to pertinent statistics, India has only implemented compulsory licenses two to three times, and the number of compulsory licenses in Thailand has gradually dropped since 2007. Despite the fact that the number of compulsory licenses is very large in developing countries. While rich governments often adopt compulsory licensing of pharmaceuticals passively and attempt to avoid direct implementation, developing countries frequently take the initiative to do so. Second, for serious illnesses like cancer as well as infectious disorders like AIDS, hepatitis B, and avian influenza, countries typically grant mandatory permits. Pharmaceutical corporations are resentful of Thailand and have opposed its expansion of the range of its licensed pharmaceuticals to chronic conditions including heart disease.

Classification implementation is used on several occasions in accordance with various objectives of drug patent compulsory licensing. A system of classification and the implementation of compulsory licensing of pharmaceutical products in China should be built from a variety of features and views as the implementation of classification is still in the exploratory stage. On the basis of urgency and public interest, both developing and wealthy nations have typically granted compulsive licensing for pharmaceutical patents in instances from outside. Only one instance of a required license has been reported thus far for the export of patented medications from Canada to Rwanda. In the American biopharmaceutical industry, compulsory licensing under patents are used more frequently as antitrust remedies.

4 Conclusion

Public health will play a crucial role in international trade discussions in the post-epidemic age. To protect the public health from the harm that an excessive expansion of patent rights would bring, pharmaceutical patent protection must be strengthened. A more effective system of mandatory licensing for pharmaceuticals will not only help China's future public health crisis and increase drug accessibility, but it will also indirectly encourage the growth of pharmaceutical businesses. Finally, the system for pharmaceutical patent compulsory licensing should be improved. The Drug Administration Law should be amended to include specific rules for the management of compulsory licensing of patented pharmaceuticals, and to improve administration, both the drugs on the list of compulsory licensing and the regular drugs should be labelled with bar codes. To offer patients who experience negative responses a quick fix so they can receive therapy right away.

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