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An Analysis of China's Compulsory Licensing System for Pharmaceutical Patents

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Abstract: With the outbreak of the COVID-19 pandemic, facing a serious public health crisis, the conflict between public health rights and private rights in pharmaceutical patents has become increasingly acute. The compulsory patent licensing system seeks a balance between these two. When faced with a choice between pharmaceutical patent rights and public health, the public's right to health should be prioritized. Establishing and improving the compulsory patent licensing system for pharmaceuticals is an important means of effectively addressing the public health crisis. Compulsory patent licensing in China is currently at zero implementation. This article discusses relevant domestic and international pharmaceutical patent compulsory licensing regulations, draws upon the legislation and implementation status of China, and proposes suggestions for improving China's compulsory patent licensing system for pharmaceuticals.

1. Introduction

The sudden outbreak of COVID-19 at the end of 2019 posed a serious threat to global public health. The long-standing conflict between private patent rights and public health rights in pharmaceutical patent protection has become particularly acute during the outbreak. When faced with the dilemma between pharmaceutical patent rights and public health, protecting the public's right to health should be prioritized. Establishing and improving a compulsory licensing system for pharmaceutical patents is a key means of effectively addressing public health crises. This article analyzes the challenges of China's compulsory licensing system for pharmaceutical patents and proposes strategies and solutions to address these issues in the face of major public health emergencies.

2. The Concept of Patent Rights and Compulsory Patent Licensing for Pharmaceuticals

A patent right is a type of intellectual property right granted by law to an inventor or assignee, granting them the exclusive right to exploit their invention for a specified period of time and the right to decide whether to authorize others to exploit it. Legal protection of patent rights is intended to encourage innovation and promote technological development. Patent protection is intended to encourage invention and the disclosure of the results of inventions, thereby promoting the

dissemination of knowledge and scientific and technological progress. The compulsory patent licensing system is essentially a system established to appropriately restrict patent rights based on public interest considerations and to prevent abuse of patent rights. The so-called compulsory patent licensing system refers to a legal system in which the intellectual property authority, when legally required, directly issues a license to a third party, without the patent owner's consent, using its administrative power. This license permits the licensee to exploit the patent without the patent owner's consent and requires the licensee to pay financial compensation to the patent owner. Drugs must be protected by patents. Without patent protection, generic drugs flood the market, preventing pharmaceutical companies from recovering their R&D costs and profits. New drug development becomes impossible, and humanity's ability to combat new diseases becomes impossible. The serious consequence of unpatented drugs is a significant threat to human health and life. Years ago, leukemia was an incurable disease. The advent of Gleevec (officially launched in China in 2002) allowed leukemia patients to take medication to prolong their lives. After Gleevec's patent expired (May 15, 2013), domestic pharmaceutical companies were able to legally produce generic drugs, significantly lower in price than patented drugs, reducing the financial burden on patients and their families. The state's inclusion of drug manufacturing under patent protection safeguards the people's right to life and health.

Without patent protection for drugs, pharmaceutical companies developing new drugs cannot recoup the massive investments they make. Investors will also be discouraged from engaging in new drug development. Humanity as a whole will suffer. Without the continuous development of new drugs to combat emerging diseases, medical advancement will stagnate. Without the protection of pharmaceutical patents, approximately 60% of new drugs would remain unavailable. At the same time, however, the patent system's protection of new drugs exacerbates public health issues in developing countries. Due to the high monopoly prices of patented drugs, people in developing countries face greater difficulties in accessing medicines.

However, patent protection is not absolute and is subject to various restrictions. Compulsory licensing, discussed in this article, is one such restriction on patent rights. A "compulsory license" is a license granted by a national administrative authority to another entity or individual to exploit a patent without the patent owner's consent. This license violates the patent owner's will and is therefore considered an "involuntary license [1]."

The concept of compulsory licensing for pharmaceutical patents first emerged in the Paris Convention of 1883. "Its purpose is to prevent patent holders from abusing their patent rights, hindering the exploitation and use of inventions, and hindering the progress and development of science and technology, thereby ensuring a balance between the interests of patent holders and the public interest and achieving the goals of fairness and justice [2]."

Articles 27 and 31 of the TRIPS Agreement, which came into effect in 1995, also provide for compulsory licensing for pharmaceutical patents. The TRIPS Agreement allows member countries to implement compulsory licensing for pharmaceutical patents, but also stipulates that these drugs may only be used domestically, effectively restricting the export of these drugs. This prevents countries without the capacity to produce these drugs from importing the drugs they need during public health crises. This problem was addressed in the 2003 Doha Declaration. The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health stipulates that developing and least-developed members may, in the event of a public health crisis caused by HIV/AIDS, malaria, tuberculosis, or other epidemic diseases, produce, use, and sell patented drugs for the treatment of these diseases within their own countries through compulsory licensing, without the patent holder's permission [1]. This WTO resolution enables countries without the capacity to produce these drugs to import inexpensive generic drugs during public health crises.

3. The Current Legislative Status of China’s Compulsory Pharmaceutical Licensing System

In 1984, China promulgated the Patent Law. Article 25, Paragraph 5, of the law stipulates that "due to the critical and special nature of pharmaceuticals and substances obtained by chemical processes, patent rights shall not be granted for such substances for the time being [3]." Pharmaceuticals were not included in the scope of patent protection at the time because China's economy was extremely underdeveloped. Patenting pharmaceuticals would have affected the public's right to life and health. The first patent law omitted pharmaceutical patent protection in order to stimulate the rapid development of domestic generic drugs, making medical expenses more affordable for more people and thereby reducing the burden on national healthcare. The 1992 Patent Law formally included pharmaceuticals and chemical substances within the scope of patent protection. The patent protection period for pharmaceutical inventions was set at 20 years. The 1992 Patent Law also provided that in the event of a national emergency, the patent authorities could directly initiate compulsory licensing of pharmaceutical patents. This brought my country's patent protection level close to the requirements of the TRIPS Agreement. The 2005 "Measures for Compulsory Licensing of Patents Involving Public Health Issues," the 2008 revised Patent Law, the 2010 revised Patent Implementing Regulations, and the 2012 "Measures for Compulsory Licensing of Patents" all address compulsory licensing of pharmaceutical patents.

Article 49 of the 2008 Patent Law stipulates: "In times of national emergency or extraordinary circumstances, or for the public interest, the Patent Administration Department of the State Council may grant compulsory licenses for the implementation of invention patents or utility model patents." Article 50 stipulates: "For the purpose of public health, the Patent Administration Department of the State Council may grant compulsory licenses for the manufacture and export of patented drugs to countries or regions that comply with the provisions of relevant international treaties to which the People's Republic of China is a party." Article 73 of the 2010 Implementing Regulations of the Patent Law stipulates: "Patented drugs mean any patented product in the medical field needed to address public health issues, or a product directly obtained by a patented process, including the patented active ingredients required for the manufacture of such products and diagnostic supplies required for the use of such products." These regulations broaden the concept and scope of patented drugs and expand their scope of application. Articles 6 and 7 of the 2012 "Measures for Compulsory Licensing of Patents" clearly state that in the event of a national emergency or extraordinary situation, or for public health purposes, the National Intellectual Property Administration may grant compulsory licenses to qualified entities.

From the above laws and regulations, it can be seen that my country has basically established an institutional framework for compulsory licensing of pharmaceutical patents. While the TRIPS Agreement permits compulsory licensing of pharmaceutical patents, China has not yet implemented compulsory licensing for any drug, and remains cautious in this regard. Many developed countries also remain cautious about such licensing, as it infringes on the private rights of patent holders, hinders innovation, and hinders the development of new drugs.

4. Problems with China’s Compulsory Patent Licensing System for Pharmaceutical Patents

4.1. Extensive Restrictions on Applicant Eligibility and Overly Narrow Scope

The legislation for China's compulsory patent licensing system primarily involves five legal documents: the Patent Law, the Patent Implementing Regulations, the Measures for Compulsory Licensing for Patents, the Measures for Compulsory Licensing for Patents Involving Public Health Issues, and the Patent Examination Guidelines [3]. Compulsory licensing for pharmaceutical patents is based on Articles 53-56 of the Patent Law. The Measures stipulate that in emergencies or

extraordinary circumstances, or for purposes of public interest, only the State Council and its administrative departments are eligible to apply. For public health purposes and export to other countries, only qualified entities or individuals may apply. Individuals are not eligible for such applications. On the other hand, while entities may apply for such applications, if they forgo the application due to limitations or a lack of funding or human resources, the final applicants are the State Council and its administrative departments. This fundamentally restricts the application for compulsory licensing.

4.2. The Amount of Compensation for Patent Holders Subject to Compulsory Licensing Lacks Clear Standards

Compulsory licensing is paid for, and the entity or individual that obtains the license must pay the patent holder a reasonable royalty [1]. The relevant laws do not specify the amount of a reasonable royalty or the criteria for determining it. The lack of clear guidance for royalties not only harms the legitimate rights and interests of patent holders but also undermines the motivation of relevant applicants to apply for patents [3]. Drug research and development requires enormous human and financial resources from pharmaceutical companies. If the state fails to provide adequate financial compensation to patent holders through compulsory licensing, this will dampen their enthusiasm for research and development. If laws and regulations do not clearly define compensation standards, negotiations between the entity or individual granting the compulsory license and the patent holder will inevitably become more difficult.

4.3. The Compulsory Licensing Approval Process is Overly Complicated and Inefficient

China's Patent Law stipulates that compulsory licensing requires the applicant to apply and submit evidence, a hearing, a review by the National Intellectual Property Administration, and objections from the parties. On the other hand, Article 58 of the Patent Law also allows patent holders dissatisfied with the implementation of a compulsory license to file a lawsuit with the court within three months. The litigation process can take more than six months. The outbreak of a public health crisis is sudden and time is extremely tight. Protecting public health is crucial to obtaining the most effective drugs to control the epidemic as quickly as possible. A complex and cumbersome compulsory licensing process could miss the best opportunity to control the epidemic [4].

5. Suggestions for Improving China’s Compulsory Patent Licensing System for Pharmaceuticals

The recent COVID-19 pandemic has demonstrated that public health emergencies are often highly uncertain and destructive, making them difficult to completely eliminate in the short term. Ensuring access to critical medicines in similar situations has become a major issue at the intersection of public health policy and intellectual property protection. While the current compulsory licensing system for pharmaceutical patents is established, it still suffers from significant deficiencies in emergency response efficiency and scope of application. Therefore, it is necessary to optimize relevant mechanisms at the legislative and institutional design levels to enhance their practical effectiveness in major public health crises.

5.1. Appropriately Relax Restrictions on Who Can Apply for Compulsory Patent Licensing for Pharmaceuticals

During major public health emergencies like the COVID-19 pandemic, large quantities of

pharmaceuticals are urgently needed. Faced with high medical costs, compulsory patent licensing for pharmaceuticals is an important way to ensure the supply of generic drugs. China's "Measures for Compulsory Licensing of Patents Involving Public Health Issues" clearly stipulate that relevant State Council departments can act as applicants to request the National Intellectual Property Administration (SIPO) grant compulsory patent licenses for pharmaceuticals. This designation makes individuals ineligible to apply, and "units with implementation conditions" also ineligible due to various restrictions. It is this uncertainty about who can apply that makes it difficult to implement compulsory patent licensing in the face of major public health emergencies. The current global trend is to impose no restrictions on who can apply. China should follow this trend and remove restrictions on who can apply.

5.2. Clarifying Compensation Standards for Compulsory Licensing of Pharmaceutical Patents

China's Patent Law stipulates that the implementer of a compulsory license must pay the patentee a reasonable royalty [5]. The amount of the royalty can be negotiated between the parties. If the parties cannot reach an agreement, the State Council's Patent Administration Department shall make a ruling. China's Patent Law, Patent Implementing Regulations, and Measures for Compulsory Licensing of Patents Involving Public Health Issues do not specify specific compensation standards for patentees [6]. Compulsory licensing represents a form of public power intervening in private rights. Compensation standards for patentees should still be based on the market value of the patented drug. The level of economic and social development of the country experiencing a major public health emergency should also be considered, allowing for necessary adjustments and case-by-case assessments of compensation standards for compulsory licensing of pharmaceutical patents. According to the United Nations Development Report, the standard for calculating compensation for compulsory licensing of pharmaceutical patents is based on the base price of generic drugs multiplied by 4%, with an increase or decrease of 2% based on the drug's level of innovation and government R&D funding [7]. This compensation standard can ensure the orderly operation of the compulsory licensing system for pharmaceutical patents during major public health emergencies while safeguarding the legitimate rights and interests of patentees [8].

5.3. Simplifying the Application Procedure for Compulsory Licensing of Pharmaceutical Patents

China's Patent Law provides patent holders with remedies against compulsory licensing. Patent holders dissatisfied with an administrative authorization may file an administrative lawsuit with court within three months of receiving the licensing notice. In the face of a public health emergency, the demand for pharmaceuticals is extremely urgent. If a patent holder files an administrative lawsuit, according to Articles 57 and 60 of China's Administrative Litigation Law, a decision must be rendered within three months for the first instance and within two months for the second instance. Lengthy litigation periods are detrimental to resolving public health crises in these critical moments. Therefore, it is necessary to establish simplified judicial review periods, clarify specific deadlines for administrative rulings and reconsideration, and streamline procedures to ensure that compulsory licensed drugs enter the market as soon as possible, thus facilitating the timely resolution of public health crises. Furthermore, during administrative reconsideration or litigation, the continued implementation of compulsory licensing should not be suspended to ensure the timely initiation of compulsory licensing for pharmaceutical patents. Any damage to the interests of patent holders can be compensated ex post through financial compensation [3].

6. Conclusion

From SARS and H7N9 to the current COVID-19 outbreak, China has frequently faced public health emergencies in recent years. These experiences remind us that while protecting pharmaceutical patents, it is necessary to continuously improve the compulsory licensing system for pharmaceutical patents to achieve a reasonable balance between the two.

The compulsory licensing system for pharmaceutical patents not only improves public access to medicines and reduces drug prices, but also ensures the timely supply of critical patented drugs during public health emergencies. Through improved systems, the public can obtain urgently needed, effective drugs while also balancing the innovation drive and economic interests of pharmaceutical companies. Therefore, establishing a scientific, reasonable, flexible, and efficient compulsory licensing system for pharmaceutical patents is a crucial guarantee for maintaining public health and responding to public health emergencies.

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