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The Implementation Status and Improvement Suggestions of Drug Patent Compulsory Licensing in China—Based on the COVID-19 Pandemic

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Objective: To refer to the legislative basis and practice of compulsory licensing of drug patents in developed countries, based on the current situation of compulsory licensing of pharmaceutical patents in China, and to improve the research on compulsory licensing of pharmaceutical patents in China.

Methods: Understand the development status of drug patent licensing at home and abroad, compare and analyze domestic and foreign countries from the aspects of applicable conditions and practical measures, summarize the existing problems of compulsory licensing of drug patents in China, and put forward targeted improvement suggestions.

Results: Compared with foreign legislative foundations and practices, China’s compulsory licensing system for drug patents lacks operability, and there are still great deficiencies and room for improvement in terms of applicable conditions and practical operations.

Conclusion: First, clarify the reasons for the application in the patent law and regulation system, expand the scope of applicable drugs, cancel the restrictions on the subject of the application, and shorten the judicial review period for the compulsory licensing of drug patents; secondly, improve the quality assurance and relief mechanism of the compulsory licensing drugs to protect the vital interests of patients; and finally, be good at using the deterrent power of the compulsory licensing system for drug patents.

INTRODUCTION

In order to improve the quality of generic drugs in China and improve the supply guarantee system, the Office of the State Council issued the "Opinions on Reforming and Improving the Supply Guarantee and Use Policy of Generic Drugs", which pointed out that "clarify the path of compulsory licensing of drug patents, implement compulsory licensing of drug patents, and improve the accessibility of drugs". The implementation plan of the opinion of the Health Commission pointed out that "study and improve the drug intellectual property protection system, compatible with the level of China’s economic, social and industrial development".

In recent years, in addition to the prevalence of infectious diseases such as AIDS, malaria and avian influenza, people all over the world have been tormented by non-communicable diseases such as hypertension, diabetes, tumors, etc., especially patients in developing countries and underdeveloped countries whose access to

The compulsory licensing system for drug patents is the only rule that restricts the patent rights of drug owners. The compulsory licensing system can combat the abuse of patent rights and monopoly and unfair competition are one of the paths. The compulsory licensing system can bring about an increase in social costs, the benefits still outweigh the costs.

Secondly, compulsory licensing can reduce the repeated development of technology to a certain extent, release social resources, and help the rational allocation of resources.

In the meantime, the private nature of patent determines the tendency of patentees to maximize their own interests, and monopoly and unfair competition are one of the paths. Compulsory licensing can combat the abuse of patent rights and maintain a good and harmonious market operation order [2].

The value orientation of the compulsory licensing system for drug patents is that "the implementation of drug patents should be conducive to the development and accessibility of drugs, emphasizing the importance of public health." People’s health and lives are higher than commercial interests, and when public health is not guaranteed, drug prices are flattened through compulsory licensing. Table 1 shows the reduction in drug prices after some countries have issued compulsory licenses for drug patents to use generic drugs, or through their deterrent power to force patented pharmaceutical companies to reduce the price of patented drugs.

METHODS

Background and motivation of compulsory licensing of drug patents

Patent are a right that protects the rights and interests of scientific and technological inventors, recognized under the existing world system. Drug patent holders can obtain pricing rights and exclusive operating rights within a certain period of time, to make up for the funds invested in early research and development. However, the territorial nature of patents and the high prices of patented medicines have reduced access to medicines for patients in some countries, resulting in the lack of patients' right to health. In certain circumstances, the rights of drug patentees need to be limited for balance. The compulsory licensing system for drug patents is the only rule that restricts the patent rights of drugs.

The compulsory licensing system for drug patents refers to a restrictive legal system in which a country's patent administrative organ authorizes the subject of a drug application to carry out a patent in accordance with the law, without the consent of the drug patentee under certain conditions [1]. It was formalized in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which entered into force in 1995, as "other uses not authorized by the patentee".

Markets, economies and public health effects

First of all, the compulsory licensing of drug patents may reduce the occurrence of patentees hindering others from applying patents reasonably, reduce transaction costs, promote the rational use of patents, and thus reduce drug prices. Granting a compulsory license by the government is a good solution when transaction costs are high, and drug patents are indispensable to the development of society or public health. Although the implementation of compulsory licensing will also bring about an increase in social costs, the benefits still outweigh the costs.

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RESULTS

The current situation and inadequacies of the domestic drug patent compulsory licensing system

Current situation: Legislatively, China’s first Patent Law promulgated in 1984, provided for a compulsory licensing system for patents, which was subsequently amended four times. There are also administrative regulations "Detailed Rules for the Implementation of the Patent Law", departmental rules "Measures for Compulsory Licensing of Patent Exploitation Involving Public Health Issues" and "Measures for Compulsory Licensing of Patent Exploitation", which jointly established China’s compulsory patent licensing system. The Patent Law has the highest effect and provides a general provision on the grounds for application, application conditions and enforcement.

Table 1: The influence of drug patent compulsory licensing on drug price.

<table>
<thead>
<tr>
<th>Nation</th>
<th>Time</th>
<th>Generic name</th>
<th>Proprietary name</th>
<th>Holder of patent</th>
<th>Decreasing amplitude (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>2001</td>
<td>Nelfinavir</td>
<td>Viracept®</td>
<td>Roche</td>
<td>40 (Patented medicine)</td>
</tr>
<tr>
<td>United States</td>
<td>2001</td>
<td>Ciprofl oxacin hydrochloride</td>
<td>Ciprobay®</td>
<td>Bayer</td>
<td>50 (Patented medicine)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>2004</td>
<td>Zidovudine</td>
<td>Retrovir®</td>
<td>Glaxo Wellcome</td>
<td>81 (Generic drug)</td>
</tr>
<tr>
<td>Thailand</td>
<td>2007</td>
<td>Clopidogrel hydrogen sulfate</td>
<td>Plavix®</td>
<td>Sanofi</td>
<td>92 (Generic drug)</td>
</tr>
</tbody>
</table>


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procedures. The Detailed Rules for the Implementation of the Patent Law mainly define "drugs with patent rights" and provide for the convergence of the provisions of Article 55 of the Patent Law with those of the TRIPS [3]. The Measures for compulsory licensing of patents involving public health issues stipulate the implementation of compulsory licensing of patents involving public health, locate infectious diseases that are subject to compulsory licensing for diseases, and stipulate the scope of infectious diseases. The Measures for Compulsory Licensing of Patent Exploitation regulate the procedures for granting, awarding fees and terminating compulsory licenses.

A system is studied from a theoretical level, then fixed through binding legal documents in order to apply it effectively at the practical level. China’s practical experience in compulsory licensing of pharmaceutical patents is zero, and it is very cautious about the implementation of the compulsory licensing system, and has not even used the system as a deterrent to patent pharmaceutical companies.

Inadequacies:

- **Unclear reasons and narrow scope for application:** Firstly, China’s Patent Law does not directly cite public health issues as a reason for issuing compulsory licenses for drug patents, but only stipulates them in the implementation rules. Article 54 of the Patent Law makes "the occurrence of a state of emergency or extraordinary circumstances in the country" or "for the purposes of the public interest" as the subject of the application. However, it is not clear in the text of the law whether "in the public interest" is merely a cause of issuance or the value of a compulsory licensing system. The pursuit of public interest is the social value orientation, is the implementation of patent compulsory licensing and even the fundamental purpose of protecting intellectual property rights, the two are logically inclusive relationship, it is a value pursuit, is a very flexible expression, even if "for the public interest" as a single application is not appropriate.

Second, the use of compulsory licenses is limited to infectious diseases that are not in line with China’s national conditions. As a populous country, China's medical security system is not yet perfect, and there is a certain gap in its innovation ability compared with developed countries, so it is not appropriate to actively exclude all drugs for the treatment of noncommunicable diseases from the scope of compulsory licensing. In contrast, other countries in the world do not take infectious diseases as a benchmark, but whether they affect public health as the criterion.

- **Eligibility restrictions for applicants:** Compared with the "proposed implementer" in the TRIPS, Article 53 of the Patent Law of the People’s Republic of China restricts the subject of the application for compulsory license to "units or individuals that meet the conditions for exploitation". First of all, how to determine whether the applicant unit or individual is eligible? Generic patented drugs need to have reverse engineering technology, a certain scale of production and other requirements, the main responsibility of China National Intellectual Property Administration (CNIPA) is the management of intellectual property rights, to judge whether an enterprise has the qualification to implement drug patents strong imitation, it is difficult to actually operate. Secondly, when the applicant applies for a compulsory patent license, he does not know whether he can succeed, so he spends a lot of resources to ensure that he has the ability to implement the strong imitation of drugs, which is too risky and does not conform to the law of the market.

When the state is in a state of emergency or extraordinary circumstances, the patent administration department under the State Council may grant a compulsory license to exploit the patent. The question is, who is granted a compulsory license? How is the implementation entity determined? None are conclusive.

- **Complicated procedures and uncertain time:** The compulsory licensing procedure for drug patents is complicated and the application period is quite long. The applicant needs to seek the consent of the patentee before filing an application with CNIPA on the grounds that the patentee has not exploited or has not fully exploited the patent, cross-patent. After CNIPA makes a decision, if the patentee or applicant is dissatisfied, he can file a lawsuit with the people's court within three months, and the second-instance final adjudication system in China’s judicial system takes a long time.

After CNIPA made the decision on compulsory licensing, the effective time was not specified. What to do if the patentee is dissatisfied with the initiation of judicial proceedings. Public health crises are often urgent and urgent, especially in outbreaks that require rapid isolation and treatment. Too cumbersome procedures in this case are not conducive to the implementation of compulsory licensing.

- **The lack of quality assurance of strong generic drugs and relief mechanisms:** Since the quality risk of strong generic drugs produced through compulsory licensing is greater than that of patented drugs, can the implementing unit ensure the safety of the drug when public health is threatened in an urgent situation? The solution of public health problems should not only be increased from the "quantity" of drugs from compulsory licensing to ensure that more patients have access to treatment opportunities, but also to ensure the "quality" of drugs and ensure that under the compulsory licensing system, there
will be no problems with the therapeutic effect of drugs. The connection between patents and drug safety is insufficient, and the supervision of relevant aspects is still in a blank state. If harm is caused, what remedies should be offered to the victim?

Provisions and practices of compulsory licensing of drug patents in developed country or region

**United State:** Although the United States advocates strong protection of patents internationally, it challenges and opposes compulsory licenses in other countries. However, this is not the case in his own country. Compared with China’s pharmaceutical patent compulsory licensing system, which mainly issues licenses through administrative means, the United States does not have administrative participation in the patent compulsory licensing system, and even does not have a clear patent compulsory licensing system, but this does not mean that the patent compulsory licensing system does not exist in the United States. The U.S. judiciary is advanced, and the restrictions on patent rights are reflected in many bills, such as the "government use" of the US federal regulations, the "emergency operation of unapproved drugs" in the Food, Drug and Cosmetics Act, the "approval of third parties to use patented technology" in the Clean Air Law, and the "antitrust" of the Sherman Act. The United States uses judicial compulsory licensing to balance the relationship between patentees and the public interest, manifested as "exceptions to the application of injunctive remedies" [4]. That is, the plaintiff's court issued a "permanent injunction" against the patent infringer's infringement, and the court ruled that refusing to issue a permanent injunction means that the infringer can continue to apply the patented technology, and the judgment result is more powerful than the administrative license, and the procedure is more simplified. And from the perspective of the scope of compulsory licensing, the interpretation that can be made is obviously much broader than the situation stipulated in China’s patent licensing system.

The compulsory patent licensing system in the United States is not only reflected in legislation, but also has rich practical experience. In 2001, the United States was attacked by bioterrorism by the anthrax virus, and in the face of a public health crisis, the government considered imitating the broad-spectrum antibiotic ciprofloxacin hydrochloride of Bayer because of drug prices and financial problems. Forcing Bayer to voluntarily reduce drug prices to 50%, the right to health of U.S. citizens was guaranteed. It is interesting to note that the number of anthrax infections in the United States at that time was only 17, and the United States considered implementing compulsory licensing of drug patents.

In 2009, as Influenza A (H1N1) virus spread around the world, the minister of U.S. Department of Homeland Security declared a public health emergency, and FDA issued an emergency authorization order for the antiviral drugs Zanamivir, Tamiflu, and Rrt-PCR influenza A (H1N1) influenza diagnostic kits, to reduce the spread and severity of the disease [5]. In terms of remedies for compulsory licensing of pharmaceutical products, compensation is obtained for serious bodily injury or death after use.

**Europe:** In January 2019, the European Patent Office (EPO) published a report entitled compulsory licensing in Europe [6], which stated that "most European countries have integrated compulsory licensing systems into their legislation, although the basis for granting compulsory licenses varies from country to country. This difference depends mainly on the civil or administrative procedures of each country. " All EU member states have provisions on compulsory licensing of pharmaceutical patents, such as L.613-16 of the French Intellectual Property Code, which stipulates that the expropriation licensing system shall be applied under the conditions of articles L.613–17 for the purposes of public health interests. The Germany Patent Law has compulsory licenses that are enforced on the grounds of public interest.

The report also states that "European countries do not frequently enforce compulsory licensing for patents." "So far, only two cases in Europe have initiated compulsory licensing of pharmaceutical patents in Germany. One case involved interferon-α active ingredients without compulsory permission (1996). Another case was a case involving the compulsory licensed drug ingredient Raltegravir (a new anti-HIV drug). The second case was the first case to be granted a compulsory license by the German Federal Patent Court and supported by the German Federal Supreme Court, and the first case to obtain a compulsory license for pharmaceutical patents in the EU.

In 2006, the European Parliament and the European Council, in line with the provisions of the General Council Resolution on the export of compulsorily licensed patented medicines to underdeveloped countries, issued Document No. 816/2006 "Regulation on Compulsory Licensing of Patents for the Manufacture of Pharmaceutical Products for Export to Countries Facing Public Health Problems" in accordance with Articles 95 and 133 of the Eu Treaty. This document does not go beyond the content of the TRIPS Agreement in substance and plays a major role in addressing the public health problems of the world’s least developed countries.

In practice, however, the EU’s approach to compulsory licensing is indeed diametrically opposed. The EU requires developing countries to carry out compulsory licensing of only 11 drugs with patent protection in the WHO list of medicines, which cannot be exceeded; requires that the patent legislation requirements of developing countries comply with Patent Cooperation Treaty (PCT) and European Patent Convention (EPC); and the EU also actively implements the "Directive 2004/48 EC of European Parliament and of the council of 29 April 2004 on the enforcement of Intellectual Security declared a public health emergency, and FDA
Property Right (IPRED)" to crack down on some generic drug industries.

**DISCUSSION**

**Improve legislation**

At present, the amendment to China’s fourth Patent Law has been implemented on June 1, 2021. However, there are still too many levels of compulsory patent licensing legislation, resulting in scattered content, insufficient effectiveness, and overlapping of some contents. It is proposed that the reasons for issuance, the scope of drugs and the compulsory licensing of patents for export drugs be stipulated in the Patent Law to raise the level of effectiveness. Secondly, the procedures and fees involved in the Detailed Implementing Rules of the Patent Law and the Measures for Compulsory Licensing of Patent Exploitation are uniformly stipulated in the Detailed Implementing Rules, to solving the problems of overlapping content and inefficiency.

**Clarify the reasons for application and expand the scope of applicable drugs:** Firstly, the inclusion of "for public health purposes" in the Patents Act as a subject of application, rather than being separately provided for in the Implementing Regulations, should be concealed as a cause of "state of emergency or extraordinary circumstances", and non–contagious diseases should also be included in the list of diseases that endanger public health. It may be stipulated that the public can apply for compulsory patent licensing if they fail to obtain drugs of quality and quantity that meet their needs at reasonable prices in China.

Secondly, article 54 of the Patent Law was deleted "or for purposes in the public interest". "For the purpose of the public interest" should be made the value goal of compulsory licensing of pharmaceutical patents, not a subject of application.

**Abolish restrictions on applicant subjects and clarify the implementing entities of government use:** The restrictions on the qualifications of the applicant are relaxed, and the premise of "having the ability to implement" is not the premise. References can be made to "intended implementers" of the TRIPS or "stakeholders" in some countries, including competitors of patented pharmaceutical companies and patients with medication needs. Even if the implementation capacity is insufficient at the time of application, after obtaining the compulsory license of the qualified Intellectual Property Administration, the applicant can mobilize resources to meet the implementation conditions, which is conducive to the rational allocation of resources and the reduction of risks.

In cases of national emergency or extraordinary circumstances, it should be made clear that the Intellectual Property Administration shall determine the enforcers of compulsory licenses. Using the existing pharmaceutical enterprises in China, a compulsory licensing committee for drug patents can be established, and in the case of government use, the National Health Commission will conduct evaluation and demonstration with the Ministry of Industry and Information Technology and the National Medical Products Administration (NMPA), and quickly select a member of the implementation committee as the implementer based on the ability of the members in peacetime, and CNIPA will make a decision to grant a compulsory license or reject the implementation.

**Shorten the period of judicial review and clarify the time for entry into force:** Public health is urgent. If the patentee is dissatisfied with the decision on compulsory licensing or the ruling on the license fee, it shall file a lawsuit with the people’s court within three months, and theoretically it can go through up to four trials. The combination of a ruling on the grant of a compulsory license and a decision on the license fee can simplify the proceedings and reduce the length of the proceedings. It can be stipulated that when the patentee raises an opposition, the patent office organizes a hearing, which is simpler and shorter than judicial proceedings.

In an emergency situation, it is impractical to wait for the judgment result of the people’s court to implement the compulsory license, and according to the provisions of the Administrative Law of the People’s Republic of China that initiating an administrative reconsideration does not affect the implementation of the administrative result, it should be made clear that the effective time of the compulsory license is when the State Intellectual Property Office makes a judgment, and the administrative lawsuit initiated by the patentee does not affect the implementation of the compulsory license.

**Improve the quality assurance and relief mechanism for compulsory licensed drugs**

Compulsory licensed drugs are developed and produced due to the urgency of time, especially when explosive diseases threaten public health, compared with drugs that are normally approved and marketed, the risk of compulsory licensed drugs is greater, and may bring additional harm to patients in the prevention and treatment of diseases.

First of all, improve the connection between the patent department and the drug safety supervision department. The drug regulatory authorities should focus on supervising and helping compulsory licenses to produce drugs of qualified quality, and closely monitor the safety of drugs after use, and closely contact the patent administration departments.

Secondly, if the patient suffers physical damage after taking compulsory licensed drugs, there should be a quick and effective remedy channel. Remedies for drug damage should be improved so that the public can use compulsory licensed drugs with confidence. It may be provided that the use of medical products in a state of emergency resulting in
serious bodily damage or death may be compensated by the State in accordance with the law. For compulsory licensed drugs, the adverse drug reaction fund compensation system in Japan and Taiwan can be used to establish a compulsory license generic drug stop loss fund, which is composed of corporate profits and government subsidies or is composed of an annual deposit paid by pharmaceutical enterprises.

**Make good use of the deterrent power of system**

The protection of intellectual property rights in pharmaceuticals is a universal norm in the world, which is conducive to creating a good atmosphere for innovation and promoting pharmaceutical innovation. Compulsory licensing complements the patent protection system and is "a remedy for the patentee's failure to comply with the instrumental and social obligations to disseminate knowledge" [7]. Therefore, the biggest role of the compulsory licensing system for drug patents is to "set aside and not use". Under the normal implementation of a patent, there is no need for compulsory licensing, as long as the patentee improperly uses the patent, or the protection of the patent endangers the public interest, it is necessary to consider compulsory licensing. The first step is often to negotiate with patented pharmaceutical companies, if a certain quantity of drugs can be obtained at a reasonable price, then the compulsory license can stop there, and there is no need to start the compulsory licensing process. Only when the negotiations are unsuccessful do the government have to take the second step: the issuance of compulsory licenses. The compulsory licensing system plays a major role in the first step of negotiations, playing a deterrent role for patent pharmaceutical companies, and the government then uses China's large market as a bargaining chip to promote pharmaceutical companies to reach voluntary licensing agreements for patented drugs or reduce drug prices.

**Limitations of the Study**

The research in this paper is based on the existing drug patent compulsory licensing system and implementation status in China. Due to policy changes, the recommendations are temporary and may not be applicable over time. In addition, China’s newly amended patent law has been formally implemented in 2021, so it will take time to realize the suggestion ‘Improve Legislation’ in the discussions. In addition, the gap in the practice of compulsory licensing in China requires localization practice for the feasibility of the system.

Future research on drug patent compulsory licensing in China will benefit from the law revision and practice to conduct more in-depth and more specific research.

**REFERENCES**