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PERSPECTIVES

The Legislative Approach and System Improvement of China's Compulsory Licensing for Drug Patents

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Abstract: Compulsory licensing for drug patents is of great significance to ensure the accessibility of drugs. Although the development of China's compulsory licensing system for drug patents has been gradually improved, there are still problems. For example, the scope of the object is not realistic, the setting of the initiating subject is unreasonable, the reasons for issuance are not clear, the duration and scope of the license are not refined, and the provisions on the exploitation fee are missing. Consequently, in order to improve China's compulsory licensing system for drug patents, it is necessary to expand reasonably the scope of the object, remove the restrictions on the initiating subject, adjust the initiating rights of different subjects, determine the duration and scope of the license and the applicability of the hearing on a case-by-case basis, and determine a reasonable exploitation fee by taking into account the national income, patent cost, market share and other factors, in consideration of the flexibly international norms and the actual situation in China.

Keywords: drug patents, compulsory licensing, public health

Introduction

In late 2019, "Corona Virus Disease 2019" (COVID-19) broke out and swept the world, and the World Health Organization classified this outbreak as an "international public health emergency", which continues to spread in many countries and regions even to this day. The epidemic has posed a great threat to public health, not only because of the highly contagious nature of COVID-19, but also because of the lack of effective drugs to prevent and treat COVID-19.[1,2] Adequate supply of effective drugs is an important guarantee for solving public health crises. In order to achieve this guarantee in public health emergencies and to alleviate the fierce conflict between drug patents and rights of public health, a compulsory licensing system for drug patents may be an appropriate choice.[3] The compulsory license of drug patents is "a non-voluntary agreement between the voluntary buyer and the non-voluntary seller imposed and enforced by the Country for the public health benefits". The compulsory license of drug patents shows the game of many kinds of rules under the background of the patent right, health right, and international law.[4–9] Just because of this, the compulsory licensing system for drug patents is both complex and controversial, and it is always a hot topic and has become one of the important issues under discussion in patent law.[10]

In fact, many countries have implemented such a system (Table 1).[11,12] Even the United States, such a highly-developed country, also once used the compulsory

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licensing system for drug patents, thus significantly increasing the domestic supply of drugs and inhibiting the spread of public health crises.[13] On September 18, 2001, soon after 911, a letter containing anthrax spores was posted to Tom Brokaw and New York Post. On September 20, in the office of a tabloid in Florida, the more fatal inhaled anthrax virus appeared. At that time, Cipro, the only drug with which anthracnose could be effectively treated in the United States, was in the duration of patent protection. The patentee was Bayer AG. People with a low income could not afford the medical expense of Cipro, USD 700, in a course of treatment. However, due to 911, people were frightened by terrorism and urgently needed to be comforted, so for the American government, the improvement of the accessibility of drug, Cipro, was the top priority.

Canada adjacent to the United States also worried about the appearance of the anthrax virus, so it granted the compulsory license for the production of Cipro in a hurry. Thus, Charles-E Schumer, the Senator of the Democratic Party of the United States in New York, urged the American government led by Bush to get the sufficient inventory of Cipro for the American people to respond to the possible extensive bioterrorism attacks. Because the United States did not have a real compulsory licensing system, and it was always against compulsory licensing. To improve the accessibility of Cipro, the American government decided to negotiate with Bayer AG. The American government threatened to grant the compulsory license according to related laws and the TRIPs Agreement, if Bayer AG did not make the expected price concession.[14] Of course, Bayer AG was not willing to directly reduce the price, but it had to reduce greatly the price of Cipro from USD1.86 to USD 0.95 per pill under the pressure from the American government.[15] As a result, the American government improved the accessibility of Cipro, as desired, and helped people to actively defeat the epidemic and panic.

The compulsory licensing system for drug patents involves two fields: the right of public health and drug patents. The patent embodies the role of stimulating innovation to promote the development of human society, while the right of public health has the ultimate goal of ensuring the survival and health of human beings.[16,17] The contradiction between drug patents, as a private right, and the right to public health, as a human right, has always existed, and this contradiction stems from the inherent monopoly of patent rights and the natural rationality of public health.[18–24] This contradiction also gives meaning to the existence of a compulsory licensing system for drug patents, because a reasonable compulsory licensing system for drug patents can balance the two rights and alleviate the conflict between them.[25] In order to build a compulsory licensing system for drug patents, which is in line with the current trend and truly effective, firstly, it is necessary to clarify the priority of the right of public health compared with the drug patent, and to ensure that the rights related to the survival and development of human beings are given priority.[26] Secondly, it is necessary to balance the interests of all parties in the compulsory licensing system. On the premise of protecting the health of population for taking medicine, it is important that the legitimate interest of drug patentees is maintained, and the public power representing public interests is prevented from interfering unduly with the dynamic balance maintained by the private patent and right of public health. Finally, in order to achieve the above-mentioned purpose of giving priority to public health, it is necessary to impose reasonable restrictions on the drug patents to prevent the abuse.[27,28]

The compulsory licensing system has been controversial since the establishment of the TRIPs Agreement, with developed countries seeking stronger patent protection for their pharmaceutical industries and developing countries hoping to provide more favorable access to primary drugs by compulsory licensing.[29] In the case of China, the compulsory licensing system for drug patents has been in place for many years and there were several public health crises in the past, but the system has never been implemented in response to the public's demand for drugs.[30–32] In order to keep in line with the development in Chinese society and public health, and the demand of Chinese for effective drugs, it is necessary to build a compulsory licensing system for drug patents which is allowed by the TRIPs Agreement. This paper aims to, firstly, review and summarize China's compulsory licensing for drug patents from the perspective of the legislative approach of the system, and find out the defects of the system; secondly, analyze the foreign practice of compulsory licensing for drug patents, and seek out useful experiences that are conducive to the improvement of China's compulsory licensing system for drug patents; finally, on the basis of the above discussion, propose the guideline and some suggestions for improving China's compulsory licensing system for drug patents.

Table 1 Case Analysis of Foreign Compulsory Licenses of Drug Patents

Case Name	Parties Involved	The Disputed Object	The Results
The Compulsory license of Plavix (2007)	The Thai government and French pharmaceutical company, Sanofi	Plavix used for the treatment of heart disease.	The Thai government issued the compulsory license.
The compulsory license of Sorafenib (2012)	The India company, Natco and the company, Bayer AG	Sorafenib used for the treatment of advanced kidney and liver cancer.	The Indian Patent Office issued the compulsory license.
The compulsory license of Efavirenz (2007)	The Brazilian government and the company, Merck	Efavirenz used for the treatment of AIDS.	The Brazilian government issued the compulsory license.
The compulsory license of Isentress (2017)	The European company, Merck and the Japanese company, Shionogi	Isentress used for the treatment of AIDS.	The German High Court in Dusseldorf, and the German Federal Supreme Court agreed to issue the compulsory license.
The compulsory license of Oseltamivir (2004)	Taiwan's Intellectual Property Office and the two companies, Roche and Gilead	Oseltamivir used for the treatment of H5N1 Avian Influenza	Taiwan's Intellectual Property Office issued the compulsory license.
The compulsory license of Cipro (2001)	The American government and the company, Bayer AG	Cipro used for the treatment of anthracnose	Bayer AG reduced greatly the price of Cipro under the pressure from the American government.

The Legislative Approach of China's Compulsory Licensing for Drug Patents and the Existing Specific Problems

The Development History of China's Compulsory Licensing for Drug Patents

Patent Law in 1984

The compulsory licensing system was stipulated in China's first Patent Law, which has been amended three times since then and has been gradually improved. However, in the Patent Law in 1984, the patents were not granted to food, drugs, chemicals and nuclear fission-related substances, and consequently the compulsory licensing for drugs patents is out of question.

Patent Law in 1992

Due to the pressure from the United States, China amended the Patent Law in 1992 in accordance with the Memorandum of Understanding on the Protection of Intellectual Property Rights between China and the United States. This amendment expanded the scope of patent protection, and gave patents to "foodstuffs, beverages and condiments" as well as "drugs and substances obtained by chemical methods". Since then, China has granted patents to drugs in a real sense and can discuss compulsory licensing for drug patents. Compared with the Patent Law in 1984, the Patent Law in 1992 mainly expanded the subject scope of compulsory licensing, which is no longer limited to "units that have the conditions for implementation". In addition, the China's Patent Office may issue compulsory licenses directly where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires.

Patent Law in 2000

Most of the amendments to the Patent Law in 2000 were made to meet the requirements of the TRIPs Agreement.[33] Since China was actively applying for accession to WTO at that time and receiving some external pressures, the amendments to the Patent Law did not make good use of the relevant flexible provisions of the TRIPs Agreement, which resulted in the high standard of intellectual property rights (IPR) protection and ignoring the actual development of IPR in China. Consequently, the intellectual property protection and market development in China was limited. Specifically, general provisions which stipulated the scope, duration and termination of compulsory licenses were mainly added.

Measures for Compulsory License on Patent Implementation Concerning Public Health Problems in 2005

In 2002, the outbreak of SARS virus posed a great threat to China's public health. In order to protect people's lives

and health, and improve the accessibility of drugs in response to such health emergencies, the Measures for Compulsory License on Patent Implementation concerning Public Health Problems in 2005 (hereinafter referred to as the "Health Measures") made statutory interpretation on the compulsory license of drugs, which clarified the scopes of "infectious diseases" and "drugs". Specifically, "infectious diseases" include AIDS, tuberculosis, malaria and other infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases; while "drugs" refer the patented products which treat the above-mentioned infectious diseases, and the products which are manufactured by patented methods. Obviously, it can be seen that the Health Measures only recognizes drugs for infectious diseases as the object of compulsory licensing.

Patent Law in 2008

The amendment to the Patent Law in 2008 was a change from the previous situation. It was no longer amended due to external pressure, but replaced by a proactive amendment based on China's national conditions. Specifically, the compulsory license is one of the main contents of this amendment. Patent Law in 2008 has a special chapter to provide for compulsory license, and this chapter is provided based on the Patent Law in 2000 with the following modifications: adding that for the purpose of public health, the patent administrative department under the State Council may grant compulsory licenses for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the People's Republic of China; adding that where the acts of exercising patent rights by a patentee have been determined as monopolistic acts pursuant to the law, compulsory licenses can be granted.[34]

Implementing Regulations of the Patent Law in 2010

In line with the revision of the Patent Law in 2008, the State Council of China approved the Implementing Regulations of the Patent Law (hereinafter referred to as the "Implementation Regulations") in 2009, which came into effect in 2010. The Implementation Regulations totals 11 chapters, including 123 articles. Chapter 5 provides for the compulsory licensing of patent implementation, and its supplementary interpretation of the Patent Law mainly includes: firstly, the meaning of "insufficient exploitation of its or his patent" is clarified, and it refers to that the manner or scale of the exploitation of patent by the patentee and/or the licensee authorized by it or him cannot satisfy the demands of the domestic market for the patented product or patented technology; secondly, the definition of "pharmaceutical product to which patent right has been granted" is explained, and it refers to any patented product, or product directly obtained by a patented technology, of pharmaceutical sector needed to address public health problems, including the patented active ingredients necessary for the manufacture of the product and the diagnostic kits needed for its use.

Measures on Compulsory Licensing of Patent in 2012

By 2012, China National Intellectual Property Administration formulated the Measures on Compulsory Licensing of Patent (hereinafter referred to as the "Licensing Measures") in accordance with the Patent Law and the Implementing Regulations of the Patent Law, and the former Measures on Compulsory Licensing of Patent in 2003 and the Health Measures in 2005 were repealed at the same time. The Licensing Measures has more detailed provisions on compulsory licensing, mainly involving procedural matters, including the procedures for the filing, acceptance, examination and decision of compulsory licensing, which is of great importance to the improvement of the compulsory licensing system.

Opinions on Reforming and Improving Policies on the Supply Assurance and Use of Generic Drugs in 2018

In 2018, the General Office of the State Council of China issued the Opinions on Reforming and Improving the Policy on the Supply and Use of Generic Medicines (hereinafter referred to as the "Opinions"), which introduced "extraordinary situation such as a serious threat to public health" into the "where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires". Furthermore, the "shortage of drugs for serious and critical diseases" is also defined as a situation where public health security and public health are seriously threatened, and the "serious and critical diseases" here should include diseases other than infectious diseases, such as cancer, cardiovascular diseases, etc. The Opinions also indicates that drugs, which might be compulsory licensed in China, is not limited to those for infectious diseases.

From the above development history of China's compulsory licensing system, it can be seen that, firstly, the early revisions of China's compulsory licensing system were influenced by the external pressure and to a certain extent detached from the actual needs of China, while the

later revisions favored the endogenous factors and gradually matched with the actual development of Chinese society.[35] But in summary, China's compulsory licensing system is still difficult to meet the actual needs. Secondly, regulations on China's compulsory licensing system for drug patents is not concentrated in one or two documents, but scattered in four layers of legal and policy documents, including laws, regulations, rules and policies. These four layers of documents are clearly defined and each has its own function, building the main framework of China's compulsory licensing system for drug patents. There are viewpoints that the compulsory licensing legislation in China has too many layers and is scattered, which is not conducive to the implementation of compulsory licensing. This paper argues that the richness and complexity of the compulsory licensing for drug patents, which is an important system for public health and intellectual property protection, makes it difficult to be regulated in one or two documents, and it is more appropriate to regulate various kinds of matters on compulsory licensing at different layers to facilitate the practical operation and accurate positioning of each document. Thirdly, China adopts strict standards for the application of compulsory licensing for drug patents, which to a certain extent reflects China's policy and determination to vigorously develop intellectual property protection. However, the overly strict regulations on the scope of the object of compulsory licensing for drug patents and the qualifications of applicants for compulsory licensing have largely hindered the practical application of the system, resulting in no case of compulsory licensing for drug patents issued in China so far.

Problems on China's Compulsory Licensing System for Drug Patents

Vague Criteria on Defining the Scope of the Object of Compulsory Licensing for Drug Patents

In this paper, the scope of the object of compulsory licensing for drug patents includes horizontal and vertical aspects. The scope of the object is understood horizontally as the drugs for which diseases should be included in the scope of compulsory licensing; the scope of the object is understood vertically as the scope of "drugs", ie, whether the active ingredients of non-final products, diagnostic tools or pharmaceutical manufacturing technology can be compulsorily licensed. The following is an analysis on the scope of compulsory licensing for drug patents from both horizontal and vertical aspects.

Firstly, in the horizontal aspect, Chinese law ignores the importance of drugs for non-infective disease to public health. After the repeal of the Health Measures, although public health crises are no longer limited to infectious diseases, China has not clarified that public health crises caused by non-infective diseases can be included in the scope of compulsory licensing. With the gradual increase in the number of patients with chronic diseases in China, chronic diseases have caused more than 80% of all deaths, and chronic diseases have gradually become a major factor affecting human health, which also indicates that the impact of chronic diseases on public health has taken a major position. Therefore, the drugs for cancer, cardiovascular disease and other chronic non-infective diseases should be included in the scope of the object of the compulsory licensing, which reflects the firm determination on safeguarding the public health of the Chinese people in the new era.

Secondly, in the vertical aspect, China's laws and regulations have narrowed the scope of "drug patents". The scope of "drug patents" itself includes the pharmaceutical compound and its manufacturing method, while Article 73 (2)of the Implementation Regulations specifies that the object of compulsory licensing for drug patents is a product, which is a tangible object. This article excludes pharmaceutical manufacturing technology, which irrelevantly narrows the scope of the object of compulsory licensing for drug patents.

Unreasonable Setting on the Subject Qualifications for Initiating the Compulsory License of Drug Patents

Firstly, the China's laws and regulations have avoided the subject of initiating compulsory license of drug patents. China's Patent Law provides that in three situations, such as emergency, the patent administrative department under the State Council may directly issue a compulsory license of drug patents, but does not specify who will initiate the administrative procedure; moreover, the Implementation Regulations evade the problem by not specifying the subject. In this regard, scholars mostly insist that the patent administrative department under the State Council should not issue directly the compulsory license with its authority, but needs a subject to initiate the administrative procedure. It can be seen that the views of scholars contradict the provisions of the Patent Law and the Implementation Regulations. The provisions are not appropriate. Because

the patent administrative department initiates the administrative procedure and issues compulsory licenses alone, it will inevitably lead to a growing concern from the patentee. More precisely, the patent administrative department acts as both a player and referee under this legal arrangement.

Secondly, the Opinions lacks hierarchy in the provisions of the subject of initiating compulsory licenses. The second sentence of point 12 of the Opinions indicates that any entity or individual who is qualified to initiate compulsory license may request China National Intellectual Property Administration for compulsory license according to law. Additionally, the third sentence specifies that in the interests of public health, the National Health Commission, the Ministry of Industry and Information Technology and the National Medical Products Administration will evaluate the situation and then put forward the proposal on compulsory license. And then a problem emerges. When both the non-official entity and relevant authorities have the right to initiate compulsory licenses, one party, who thinks the other would initiate the compulsory license, might be indolent to do. In practice, the relevant authorities often do not take the initiative to put forward the proposal on compulsory licenses, because the non-official entity can initiate compulsory licenses.

Thirdly, the regulations impose severe restrictions to the qualifications of subject for initiating compulsory licenses. In the Opinions, the requirement that the entity or individuals should be qualified to initiate compulsory licenses indicates that China has imposed severe restrictions on the non-official entity to apply the compulsory license. The "qualification" is a concept which needs to be evaluated, and it is closely related to the capacity of pharmaceutical production and generics. In practice, due to the urgency of infectious diseases, the patent administrative department has no enough time to evaluate the "qualification", therefore this requirement is not conducive to initiate the compulsory license, and then impede the solution of public health crisis.[36]

The Concept Related to the Reason for Issuing the Compulsory License of Drug Patents is Unclear and Logically Incoherent

Firstly, the concept related to the reason for issuance is unclear. At present, this problem is widely criticized by scholars and the relevant provisions are difficult to be applied because of the problem. Specifically, the concept of "a national emergency" and "any extraordinary state", which are provided in the Licensing Measures and Patent Law in 2008, are not clearly defined. Although the Opinions, which has low legal effect, provide a little explanation on the above-mentioned concept, it is not enough to support the relevant provision to be applied.

Secondly, the logic of the reason for issuance is not smooth. The Patent Law juxtaposes "the public interest so requires" and "a national emergency" as the reasons for granting compulsory licenses, which is unreasonable and easily leads to confusion in logic. The meaning of "the public interest so requires" is very broad and rich, and it involves many aspects, so it is not appropriate to be stipulated as a reason for compulsory licensing. Moreover, it is a good proof that Article 31(b) of the TRIPs Agreement provides "public non-commercial use" instead of "the public interest so requires.

The Implementation Period and Scope of the Compulsory License of Drug Patents are Not Clearly Defined and the Hearing System is Unreasonable

Firstly, the relevant provisions on the implementation period and scope of the compulsory license are absent. The implementation period and the scope are closely related to the interests of the patentee, and if the original period and the scope once be exceeded, it will bring losses to the patentee. In order to protect the rights of patentee, and balance the interests of the public and patentee, it is necessary to define the implementation period and scope of the compulsory license scientifically. Article 55(2) of the Patent Law only provides the determination of period and scope on the grounds of individual case analysis, without specifying general provisions on how to determine the implementation period and scope of the compulsory license. It is not conducive to the protect the rights and interests of the patentee.

Secondly, it will violate the principle of balance of interests to exclude hearing procedures. Article 18 of the Licensing Measures stipulates that hearing procedures shall not be applied, in the event a request for a compulsory license is made under Article 49 or Article 50 of the Patent Law. It indicates that the hearing procedure does not apply where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires. This provision ignores the situation of public health crisis caused by chronic diseases. The threat of chronic diseases to public health is not as urgent as infectious diseases. At this point, it still excludes the

hearing procedure, it seems that the provisions are too "sensitive" and do not pay attention to the patentee's right to hearing. Therefore, in the face of public health crisis, it is not appropriate to exclude blindly the hearing procedure.

The Standards for Exploitation Fee of Compulsory License are Absent

Article 57 of the Patent Law stipulates the standards for exploitation fee of compulsory license. More precisely, an organization or individual which has been granted compulsory license shall pay reasonable exploitation fee to the patentee, or the standards for exploitation fee is made pursuant to the provision of the relevant international treaty participated by the People's Republic of China. Moreover, the amount of exploitation fee shall be negotiated between both parties. If both parties cannot come to an agreement, the amount shall be decided by the patent administrative department under the State Council. Nevertheless, the word "reasonable" in this article is too vague and difficult to implement in practice. The lack of specific standards undoubtedly bring difficulties to the determination of the amount of exploitation fee.

The Foreign Practice of Compulsory Licensing for Drug Patents and Enlightenment

The Legal Practice of Compulsory Licensing for Drug Patents in Developing Countries

Thailand

According to the Patent Law of Thailand, the compulsory license could be granted in four situations, including (1) non-working or inadequate working of patents so as to meet the local demand for the patented products (Article 46); (2) use for working of dependent patents (Article 47 and Article 47 bis); (3) public non-commercial use of patented substances for meeting the public needs (Article 51); (4) use for public interest due to war or national emergency (Article 52). According to the law of Thailand, the compulsory licensing system is assumed as a mechanism to encourage local work and free competition (when the first or second situation is applied), and authorize to use patented products for the public benefits (when the third or fourth situation is applied). In the first and second situations, the compulsory license is granted to private competitors. In the third and fourth situations, the compulsory license allows the state agencies to use the patented substance to meet public demands.[37–39]

On January 25, 2007, the Thai government granted a compulsory license to Sanofi, a French pharmaceutical company, for the drug "Plavix", which is used to treat heart diseases. The main reason is that the Thai Minister of Health considers that the price of "Plavix" is much higher than that which is set in the civil health program and seriously affects the accessibility of drugs. The minister expects the price of the generic drug to be reduced by 90% to as low as 20 cents per pill after compulsory licensing. This is the first time that the scope of compulsory license has been extended to chronic diseases, which has moved greatly the "cheese" of pharmaceutical companies in developed countries. Therefore, it has triggered much international controversy and retaliation from pharmaceutical companies. The company, Abbott, announced that it would stop selling its new drugs in Thailand and subsequently withdrew seven applications for the registration of newly developed drugs in Thailand, five of which were used for chronic diseases. The compulsory license may incur countermeasures, but it is necessary for the public health in Thailand. Thailand's attempt to extend the compulsory license to non-infective diseases is a good example of how developing countries protect their public health and play the game with pharmaceutical companies which hold the patent.[40–46]

India

The Patent Law of India in 1970 is a comprehensive legislation promulgated by India after its independence. The compulsory license is specified in it. A clear strategy is proposed in this law. That is, the monopoly of multinational companies should be eliminated, and the barriers in the former regime which prevent local companies from producing patented drugs should be removed. In 2005, India further amended the patent law. In this amendment, flexible provisions in the TRIPs Agreement and Doha Declarations were fully used for reference,[47,48] and the provisions on compulsory license for drug export were added. After 2005, compulsory licenses were issued frequently by Indian government. Although these issuances were very controversial, the system still made great contributions to the accessibility of drugs for Indian, and international public health.[49,50]

In 2009, Sorafenib, a drug for advanced kidney and liver cancer, entered the Indian market and began sales. The main effect of Sorafenib is to extend life expectancy

by four to five years for kidney cancer patients and by six to eight months for liver cancer patients. The drug costs INR 280428 (about USD 5700) for one month of treatment in India, making it difficult for the average patient to obtain such a high-priced drug. So the India company, Natco, on the base of the high price and the fact that it was not yet fully marketed in India, sought a voluntary license from Bayer, the manufacturer of Sorafenib, in 2010, hoping to sell the drug for INR 8800 to make it more affordable to patients. However, Natco's request to seek a voluntary license was denied. And then, three years after the grant of the patent, Natco applied for a compulsory license according to Article 84 of the Indian Patent Act. The Indian Patent Office approved the application for three reasons: that Sorafenib was too expensive, that Bayer did not actually meet the reasonable demand of the public, and that it did not exploit its patent in India. In this case, in regard to the meaning of "the exploitation of its patent in India", India clarified that the drug import did not fall within the scope of "the exploitation of its patent in India". Therefore, the compulsory license could be granted, which could prevent the abuse of patent rights and avoid the situation where the patent was protected in India without benefiting the Indian people.[51]

Brazil

In 1996, to implement the TRIPs Agreement and avoid the sanction from "Section 301" of United States Trade Law, Brazil amended the Industrial Property Law. According to Article 68 of this law, the compulsory license would be granted, where the patentee abuses the patent or the economic rights, or in the following two situations (1) the patent has not been exploited in Brazil; (2) commercial exploitation of patents does not meet the market demands. [52,53] The clause that "the patent has not been exploited" means that the patented product has not been manufactured or sufficiently manufactured in Brazil or the patented technology has not been fully used. Furthermore, if the patent has not been exploited on account of economic infeasibility, then the import of patented products, instead of the compulsory license, is allowed. It can be seen that the requirement on local exploitation of patents is an important reason for the issuance of the compulsory license in Brazil.

Brazil has been implementing a so-called "anti-AIDS program" since the 1990s to reduce the drug price, mainly through domestic production of generic drugs and negotiated price discounts for drugs. Despite the program succeeds, the Brazilian government's investment in the program still has grown rapidly. Part of the reason is the increased demand for second-line antiviral drugs "Efavirenz". "Efavirenz", which is included in "anti-AIDS program", costs USD 1.59 per pill in Brazil, compared with USD 0.45 per pill for generic drugs manufactured in India. On April 25, 2007, Brazilian government declared Efavirenz falling within the "public interest" as the first step in the compulsory licensing process. After the Ministry of Health rejected Merck's offer of USD 1.10 per pill, the Brazilian government took the final step in the compulsory licensing process by issuing a license to import a generic version from India and paying Merck 1.5% of the total price of patented drugs as exploitation fee. As the Brazilian government claims, the import of generic drugs will save the "anti-AIDS program" USD 30 million annually.[54,55]

Provisions on Compulsory Licensing for Drug Patents in Developed Countries and Regions and Their Practices

Germany

The Patent Law in Germany was promulgated in 1980 and amended recently on October 8, 2017. In the last version, there are 12 chapters and 147 articles. Among them, Article 24 provides the conditions, types, and exploitation fees of the compulsory license, specifically including conditions of compulsory license, compulsory licenses of dependent patent, compulsory licenses of plant cultivation patent, compulsory licenses of semiconductor technology patent, compulsory licenses for insufficient exploitation, exploitation fee for a compulsory license, and the transaction of compulsory license together with the enterprise exploiting the patent. From this article, it can be seen that the compulsory license of drug patents is not a special type in German patent law and regulated by the general provisions, which may be related to the highly developed pharmaceutical industry in Germany. The compulsory licensing system for drug patents does not need to be specially stipulated. Even when public health crises break out, Germany still can support sufficient drugs depending on its powerful pharmaceutical ability. Because of the highly developed pharmaceutical industry, the intellectual property protection, more than the compulsory license, further confirms to the interests of Germany.

Since 2014, the applicant, a European subsidiary of Merck, and the respondent, the Japanese company

Shionogi, have been negotiating a license for a patented drug, "Isentress", for the treatment of AIDS, but they have failed to reach an agreement. In 2016, the Merck subsidiary filed a request for a compulsory license of the patent in question to the German High Court in Düsseldorf and applied for a temporary injunction to allow the plaintiff to continue selling the drug with related patented ingredients. In August 2016, the court ruled that the plaintiff's request was granted pursuant to Article 24(1) of the German Patent Act. The German Federal Supreme Court dismissed the appeal and upheld the original judgment in July 2017.

Taiwan

The Patent Law in Taiwan was amended in 2019. However, this amendment did not update the provisions on compulsory license. As a result, the related provisions were similar to those in the Patent Law in 2013. According to Article 87(2), the Intellectual Property Office would issue the compulsory license on request, in the following three situations, including (1) in order to improve the public interests, the patent is exploited in the non-commercial way; (2) the new invention or patent for utility models cannot be exploited without using the previous invention or patent for utility models, and the new one has more economic significance and technological progress compared with the previous; (3) the patentee restricts the competition or implements unfair competition, which is forbidden by the court or the Taiwan Fair Trade Commission (TFTC).

In 2004, the H5N1 Avian Influenza virus posed a significant threat to the public health of people in Southeast Asia. Taiwan's Intellectual Property Office issued a compulsory license for the drug, Oseltamivir, for the following two reasons. Firstly, the threat of the avian influenza virus was imminent. Although no one in Taiwan was infected at the time, the avian influenza virus had caused 133 infections and 68 deaths in Chinese mainland. Furthermore, Taiwan was in the middle of the migratory path of migratory birds, and residents in Taiwan have frequent contacts with people in Southeast Asia. So it is necessary to Taiwan to make adequate countermeasures. Secondly, the inventory of antiviral drugs was insufficient. Because every country needed large quantities of the drug at that time, the demand exceeded the supply. The amount of drugs available in Taiwan could only meet 0.7% of the public demand, which was far below the 10% recommended by the World Health Organization.

Roche, which is the manufacturer of Oseltamivir, was very unhappy with the approval of the compulsory license and strongly questioned the pharmaceutical ability of companies in Taiwan. However, finally neither Roche nor Gilead, which are both the patentee, filed a lawsuit for various reasons during the appeal period. In June 2006, the drug produced in Taiwan had reached 10% of the public demand and met the need to fight the epidemic.

Enlightenments

To sum up, it can be seen that the compulsory license is a "magic bullet" more than for developing countries to deal with public health crises, and it is often used as well by developed countries and regions as an important tool to meet their own needs in facing public health crises.[56] Since the 21st century, compulsory license has more frequently issued in developing countries, such as Africa, Asia, and Latin America, which indicates that developing countries and regions have a higher desire for compulsory licensing. From the above cases, it is easy to find that developed countries and regions issue compulsory license mostly because of sudden public health crises, while developing countries and regions are gradually expanding the scope of compulsory license to chronic diseases. In this regard, China, as a developing country, needs to face up to the actual needs of domestic public health development and consider the following three points in improving the compulsory licensing for drug patents.

Considering the Degree of Public Demand for Drugs as a Factor for the Compulsory License

Article 48(1) of the Patent Law stipulates that the patent administrative department requires that the patentee has not implemented or fully implemented the patent as a requirement to grant compulsory licensing for implementation of the patent, which is different from the relevant provisions in India. Indian provisions prefers to consider the public's demand for medicines to grant compulsory licensing. In comparison, the Indian regulations are more in line with the concept of issuing compulsory licenses sparingly and prudently, which is of positive significance to protect the rights and interests of patentees and ensure the normal operation of the innovation mechanism. Therefore, in order to adapt to the new concept, China should transform the original claim to the public's demand for drugs, so as to rebuild compulsory licensing system for drug patents.

Breaking Through the Restriction That Only Drugs for Infectious Diseases Could Be Licensed Under Compulsory License of Drug Patents

Developing countries, such as Thailand and India, have gradually expanded the scope of compulsory licensing for drug patents to chronic diseases including heart diseases. This trend indicates that the traditional scope of compulsory licensing which only contains the drugs for infectious diseases has changed, and the drugs for chronic diseases should be included according to the need of public health. Samira Guennif, a scholar, has praised Thailand's compulsory licensing and believes that the practice in Thailand protects the public health, and reduce the price of drugs for chronic diseases, and improve the accessibility of drugs. China faces a situation very similar to that of Thailand, with low per capita income, low capacity for drug research and development, and a large number of patients with chronic diseases, making it more difficult for the Chinese to get effective drugs. Therefore, China should also bring the Drugs, which have as much to do with public health and are used for serious chronic diseases, into the scope of compulsory licensing, so as to meet the public's demand for drugs for chronic diseases.

Reasonably Defining the Connotation of the Public Interest in Compulsory Licensing for Drug Patents[57]

The compulsory licensing practice in Germany and Taiwan has provided a new perspective for defining the connotation of the public interest. The German courts have clarified that the public interest should be recognized where patients are particularly dependent on a certain drug and the lack of the drug or the use of other drugs may produce serious side effects and increase the risk of death. Moreover, the practice in Taiwan indicates that the connotation of public health has been expanded. When the public health is seriously threatened, but no outbreak of real crisis, a compulsory license still can be issued for the public health interests. Indeed, the concepts of public health and public interest are inherently vague. Because the two concepts play an important role in determining the legitimacy and rationality of compulsory licensing for drug patents, they need to be defined by a set of appropriate criteria. The practice in Germany and Taiwan provides a new perspective for consideration. By learning from the experience of Germany and Taiwan, China needs to rebuild the compulsory licensing system for drugs patents, which integrates the functions of prevention and remediation and is in line with national conditions.

Improvement of China's Compulsory Licensing System for Drug Patents

Guiding Principles

Firstly, China's compulsory licensing system for drug patents should not only be based on the present, but also consider the future. China should be fully aware of its actual situation, the burden not only from infectious diseases, but also from the chronic diseases that have become the most important factor to damage to the public health. Therefore, China should take into account its own public health level, medical level, drug development level, institutional characteristics and other actual conditions to construct and improve the compulsory licensing system for drug patents. Moreover, in view of the emergence of new diseases and the unpredictability of sudden public health crises, it is unwise to set up strict and clear criteria on the scope of the object and the reasons of compulsory licensing. The compulsory licensing procedure should be set up to take into account the occurrence of such unpredictable situations, shorten the process for timely implementation of compulsory licensing, when necessary, to improve the accessibility of drugs.

Secondly, the balance of interests should be maintained and the accessibility of drugs should be improved. The issuance of compulsory license inevitably stirs up two types of interest balance, one between the patentee and the public interest, and the other between the country granting the compulsory license and the patentee's country. Given the impact of the balance in these two pairs of relationships on incentive mechanism and international relations, their importance is self-evident. The process of improving the compulsory licensing system for drug patents is a dynamic process of constantly balancing interests, and it is necessary to adhere to the balance of interests as a guide to improve the system, especially on the premise of giving priority to the public interest, the patentee's interest cannot be interfered excessively, such as exceeding the statutory duration of compulsory licenses, no restrictions on the applicable population, etc. In addition, it is most important to improve the accessibility of drugs in the compulsory licensing system, while developed countries hope to implement the stricter compulsory licensing system to protect the interests of pharmaceutical companies which hold the patent. In this regard, what China needs to do is to translate the favorable achievements of developing countries into domestic laws for

application. In this process, China's compulsory licensing system for drug patents should not only conform to international norms, but also be set up in accordance with its domestic actual situation. In brief, the ultimate goal of all this is to fully improve the accessibility of drugs.

Suggestions on the Improvement of Compulsory Licensing System

Establishing a Flexible Criterion on Defining the Scope of the Object

The flexible criterion should break through the traditional restrictions at the horizontal aspect, which extends the scope of drugs from for infectious diseases to for serious chronic diseases. China's problems on the scope of the object of compulsory licensing for drug patents at the horizontal aspect is mainly shown in the following two points. Firstly, the provisions on the scope of "drugs" on the compulsory licensing system are relatively scattered, and the higher the level of legal force, the less the content of rules. On this issue, the scope of objects of the compulsory licensing systems in other countries and regions is mostly provided in the form unified legislation. This paper prefers these legislative practices which can reflect the importance of the scope of the object in the compulsory licensing system and show the scientific nature of the compulsory licensing system. Secondly, back to the practice of developing countries and regions, Thailand and India do not pay much attention to the voices of developed countries and make full use of the flexible provisions of international norms to improve the accessibility of drugs and meet the people's right to access to drugs. Compared with the foreign regulations and their practices, this paper argues that China should learn from their useful experience and enact provisions on the scope of objects of the compulsory licensing in the form of unified legislation. In particular, on this issue that whether a drug can be compulsorily licensed, China should learn from the regulations of India and other countries, and then determine which drugs can be compulsorily licensed on the basis of thinking whether the production of drug can meet the demand, whether the price of drug is affordable to most people, whether the efficacy of drug is significantly higher than that of similar products, and the degree of the public health crisis.

The flexible criterion should break through the traditional restrictions at the vertical aspect. Drug patents refer to inventions in the pharmaceutical field. As can be seen from the preceding paragraph, the object of compulsory licensing for drug patents includes not only the pharmaceutical produce and diagnostic tools, tangible objects, but also pharmaceutical manufacturing technology, the intangible object. The manufacturing technology is very important for pharmaceutical production, and in many cases drugs cannot be produced without the manufacturing technology licensed. In short, it is necessary to extend the scope of the object of compulsory licensing at vertical aspects, and make sure manufacturing technology be included.[58,59]

Reasonably Formulating Provisions on the Initiating Subject and Relaxing the Restrictions on the Qualification of Subjects

Most of the foreign regulations do not impose any restrictions on the initiating subject. For example, Article 107 (1) of the Korean Patent Act defines the initiating subject of compulsory licensing as that "any entity or individual who intends to implement the patented invention". The meaning of this provision is no different from the term "proposed user" in the TRIPs Agreement. In practice, if the initiating subject is required to have "the conditions for implementation", it is inevitable that there would be a procedure by which the qualification of initiating subject need to be examined. As a result, the procedure would consume valuable time of the anti-epidemic and bring the examining authority the problem of how to assess whether the initiating subject meets the "conditions for implementation". In short, the restriction on the initiating subject is unnecessary, and should be relaxed.

The relevant department under the State Council plays the role of "final safeguard" on the initiating subject. In practice, when a public health crisis may occur or has already occurred, the non-official entity and the relevant department under the State Council should actively pay attention to the crisis. It should be avoided that the relevant department negatively perform its duties because the non-official entity has the right to initiate compulsory licensing. The act of omission from the relevant department may aggravate the crisis. Therefore, the relevant department under the State Council should be imposed the statutory obligation to put forward the proposal on compulsory licenses. When the non-official entity has nothing to do and the situation has reached the condition that a compulsory license can be issued, the relevant department is obliged to request the National Intellectual Property Administration to issue a compulsory license.

Re-Examining the Reasons for Issuance in Terms of Factors Affecting Drugs Accessibility and the Degree of Public Health Crisis

From the case of Taiwan, it is obvious that the epidemic would break out seriously without enough drugs. Therefore, the insufficient quantity of medical supplies, which is not conducive to epidemic prevention, can be a reason for granting a compulsory license to meet the legitimate needs of the public. Article 49 of China's Patent Law juxtaposes "a national emergency", "any extraordinary state of affairs occurs" and "the public interest so requires", which is not conducive to the implementation of compulsory licenses. In France and India, the main reason for granting compulsory licenses is the accessibility of drugs, based on the considerations about the quantity, quality and price of the drug. The French and Indian regulations hold the primary mission of compulsory licensing for drugs patents. The primary mission is to improve the accessibility of drugs in response to public health crises, and establish clearer and more reasonable criteria for compulsory licensing. It is easier to be applied compared with Article 49 of China's Patent Law and could be used as a good reference for the improvement of Chinese law.

Therefore, when the reasons for granting compulsory licenses of drugs are determined, it is necessary to consider the quantity, quality and price of patented drugs (ie factors affecting the accessibility of drugs) as well as the degree of public health crisis, and to set up a reasonable criterion for granting compulsory licenses in order to meet the needs of the actual development of public health in China.

Determining the Scope and Duration of the License on a Case-by-Case Basis and Setting Up a Scientific Hearing Procedure

From the perspective of the resolution of public health crisis, it is not appropriate to set a specific fixed duration for the compulsory licensing for drug patents. It is advisable that the patent administrative department determines the duration of compulsory license according to the degree of the crisis itself and the scope of its impact. Furthermore, the duration should be a variable period, allowing it to be changed due to the development of the public health crisis, and if the crisis is still difficult to be eliminated within the expected period, it can be extended after listening to the opinions of the parties concerned. In addition, the scope of compulsory licensing should be determined on a case-by-case basis. In the case of chronic diseases and diseases requiring long-term drug use, such as AIDS, the scope of the compulsory license can be determined according to the population covered by the relevant government health insurance, while in the case of public health crises caused by other infectious diseases, the number of people to be covered by the compulsory license should be more, and it is not appropriate to impose any restrictions.[60–62]

For the hearing system, its significance is to maintain the parties' right to make statements and objections, and it is a platform for parties to communicate and dialogue. In China's compulsory licensing system for drug patents, hearing procedures is not applied where a national emergency or any extraordinary state of affairs occurs, or the public interest so requires. It is not favorable to the patentee in the case of a public health crisis caused by a chronic disease, because a public health crisis caused by a chronic disease is not urgent and highly contagious, and the number of patients does not rise sharply within a short period of time. So it is not appropriate to exclude a hearing procedure at this time. Therefore, the main consideration on the necessity and feasibility of a hearing is whether the application of hearing procedure would impede the resolution of the public health crisis in time. If the situation is urgent, there is no need to apply a hearing procedure; while if a compulsory license is required due to a chronic disease, it is necessary to apply a hearing procedure to protect the rights and interests of the parties.

Establishing a Standard for the Exploitation Fee in Line with the Actual Situation in China

The exploitation fee is a "corresponding price" paid by the licensed party, and also the key to safeguard the rights and interests of the patentee. The TRIPs Agreement stipulates that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. Patentees and countries issuing the compulsory license may have different views that "adequate" should be understood as sufficient or appropriate. Common sense indicates that "adequate" should be understood as appropriate. If it is understood as sufficient compensation, then the exploitation fee will be no less than the original market price of the patented drug. In that case, the value of the compulsory licensing system will be erased and no economical benefit will be reflected. In this regard, Canada's Act C-9 stipulates the formula for calculating the exploitation fee for compulsory licensing, which is: (1+UNHDI–the rank of importing members)/UNHDI×0.04. In the formula, the higher the United Nations Human Development Index, UNHDI, the more developed the country's economic and social level. For a country, the number of UNHDI is invariable in a certain period of time, therefore, from the formula, the higher the rank of the importing member, the higher the exploitation fee applied. Moreover,

Switzerland determines the exploitation fee based on the economic value of authorization, the level of development, and the degree of the public health crises and humanitarian urgency in the user's country. India takes into account the nature of the invention, the costs incurred by the patentee in making the invention or developing it, obtaining the patent and keeping it valid, and other relevant factors, to determine the exploitation fee. The relevant EU's law provides that in the event of a national emergency or any extraordinary state of affairs occurs, or in the case of a compulsory license for public non-commercial use, the exploitation fee does not exceed 4% of the total price of patented drugs, paid by the importing country. The foreign provisions on the exploitation fee of compulsory license do not take the sufficient compensation as the standard. In addition, some scholars argue that the expected market share of the generic drug, the nature of the disease treated by the drug, the type of drug involved, and the research and development cost should be considered in determining the exploitation fee.

Therefore, this paper argues that the following points should be taken into consideration in constructing China's compensation system for compulsory licensing: firstly, it should be human-centered and adhere to the priority of public health; secondly, it should be simple and easy to be applied, and could determine efficiently the exploitation fee; thirdly, it should respect and protect the interest of patentees and make them receive reasonable compensation which could be monetary or non-monetary; fourthly, it should be easy to supervise and could prevent the situation that are contrary to the purpose of compulsory licensing; fifthly, it should be constructed in accordance with the income level of the Chinese people, the economic value authorization, the urgency of the humanitarian crisis, and the research and development cost of the drug patent.[63]

Conclusion

The compulsory licensing system for drug patents, as a system to restrict patent rights and improve the accessibility of drugs to protect public health, has positive significance for the sound development of human society.[64] To improve China's compulsory licensing system for drug patents, we should rethink the existing relevant laws and regulations based on the actual situation in China. To be more specific, firstly, the provisions should pay attention to the impact of chronic diseases on China's public health, and the important role of pharmaceutical manufacturing technology in the scope of the object of compulsory licensing. Secondly, the provisions should relax the restrictions to make the initiating subject no longer be limited to "units that have the conditions for implementation", and make the relevant department play the role of "final safeguard" on the initiating subject. Thirdly, the provisions should take the degree of public health crisis and the accessibility of drugs as the compulsory licensing considerations, to avoid the confusion of the concept and logic. Fourthly, the provisions should reasonably determine the scope of the compulsory license and the implementation period with the goal of solving public health problems, and decide whether hearing procedures should be applied according to the degree of urgency. Fifthly, the amount of exploitation fee should be fixed by both parties in consultation. Where the parties fail to reach an agreement, the patent administrative department under the state council shall adjudicate based on consideration of the expected market share of the generic drug manufacturer, the nature of the disease treated by the drug, the type of drugs involved, the research and development cost, and the national income.

Disclosure

The authors report no conflicts of interest in this work.

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