Drug Patent Link System in CPTPP and China's Response

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Abstract. With the reform of the international intellectual property system, the intellectual property rules in regional trade agreements are gradually leading the development of the international intellectual property system.On September 16,2021, China formally applied to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The CPTPP intellectual property rules will have a profound impact on China's intellectual property legal system. CPTPP stipulates the drug patent link system, and China is also trying to build a drug patent link system. In order to integrate with CPTPP intellectual property rules and build a drug patent link system in line with China's national conditions, it is suggested to further clarify the patent availability standards of pharmaceutical inventions, simplify the drug marketing approval procedures and improve the patent invalidation procedures.

Keywords: CPTPP; drug patent link; drug approval; patent review

1. Introduction

In order to balance the interests between generic drug companies and innovative drug companies, countries especially the United States, have established a drug patent link system (Pharmaceutical Patent Linkage System), which means link the marketing approval of generic drugs with the expiration of innovative drug patents to avoid possible patent infringement. With the revision of the Patent Law, China has initially established a drug patent link system. In the context of China's application to join the CPTPP, relevant systems also need to be adjusted.

2. Drug patent link system in CPTPP

2.1. Provisions on drug patent link in the CPTPP

The drug patent link system requires the drug regulatory authorities not only to examine the "safety and effectiveness" when reviewing the drug registration application and making the approval decision, but also to investigate whether they infringe patent rights to a certain extent. The system is regarded as an effective early patent protection mechanism by protecting the patent, considering the interests of generic drug companies and giving the first generic drug companies the data protection period. CPTPP is a regional trade agreement with the highest level of protection so far. China officially applied to join CPTPP, which reflects the determination and motivation to improve the intellectual property protection

standards as well as points out the direction for the development and improvement of China's intellectual property system. Article 18.53 of the CPTPP stipulates the drug patent link system.

2.2. The Origin and Development of Drug Patent Link System

The drug patent link system first appeared in the Hatch-Waxman Act in the United States, and the establishment of the system greatly stimulated the vitality of the pharmaceutical market. Since then, the United States has been committed to introducing the system to countries including Canada, Australia, South Korea and Mexico. In the United States, a new drug applicant must submit a new drug application (NDA) to the Food and Drug Administration (FDA) with a product patent and method patent directly related to the active ingredient of the new drug. When the NDA is approved, the FDA will input all the valid patents information submitted at the same time as the NDA into the Drugs approved by Treatment Equivalence Evaluation, also known as the Orange Peel Book (Orange Book). Generic drugs that use data from clinical trials of registered drugs need to enter the FDA by simplifying Abbreviated New Drug Application (ANDA). The FDA requires the applicant, when submitting the ANDA, must make at least one statement about each registered patent involved in the declared generic drug: patent does not exist, patent has already expired, there is a valid patent but listed after patent expiration, patent is invalid or not infringing.

When accepting ANDA, FDA will submit the information involving patent registration submitted by ANDA applicants to USPTO for record, and get the USPTO information feedback on the patent status of the drug, which will serve as the basis for FDA review. The interconnection between FDA and USPTO when patent review is involved in the drug registration process can minimize the probability of FDA approving ANDA infringing registered patents.

3. Development and problems of the drug patent link system in China

3.1. The Development of the Drug Patent Link System in China

The early Patent Law clearly stated that drug patents are not within the scope of patent protection. In October 2017, the General Offices of the CPC Central Committee and the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices, requiring exploring the establishment of a drug patent link system, reducing the risk of patent infringement and encouraging the development of generic drugs.

In the trade war between China and the United States, the latter has been committed to promoting the establishment of a drug patent link system in China. After several negotiations, China and the United States reached the first phase of the Economic and Trade Agreement on January 15,2020. The China-US Economic and Trade Agreement determines the drug patent term compensation as the compulsory obligation of the contracting parties, and the response of China's new Patent Law is the performance of the fulfilling contracting obligations. Article 42 of the newly revised Patent Law in 2020 stipulates the relevant contents of extending the drug patent period and compensates the time occupied for the marketing approval of new drugs; Article 76 stipulates the basic contents of the drug patent link system.

3.2. Problems and challenges of China's drug patent link system

3.2.1. Restrictions on the scope and patent types of registered drugs in China are lacked. The current drug patent link system does not limit the scope of drugs with registered patents. Article 18 of the current Measures for the Administration of Drug Registration stipulates that the applicant shall provide a description of the patent of the applicant or others in China; if the patent exists in China, the applicant shall submit a statement that the patent does not constitute infringement. In this case, a drug patent linkage system will be established, and a series of patent infringement lawsuits against ordinary applicants will be filed. Applicants are prone to get caught up in patent infringement disputes and delay the launch of generic drugs, which reduces applicants' enthusiasm for further research and commercial

drug trials, while the overly cumbersome review and approval process also affects the public's access to drugs.

3.2.2. The provisions of "proposed infringement" in the Patent Law need to be improved. Article 69 of the Patent Law stipulates that "manufacturing, using or importing patented drugs or patented medical devices for the purpose of providing information needed for administrative examination and approval, or specially manufacturing or importing patented drugs or patented medical devices" is not a patent infringement. The provision is known as the "Bolar exception "in China's patent law. However, the above provisions only refer to the provisions of the US patent law on patent infringement, ignoring the proposed infringement provisions. If the drug patentee brings a patent infringement lawsuit against the drug registration application and requires the confirmation of the infringement of the later drug registration application, the court may lack a clear legal basis for ruling. As a result, the patentee can only file a patent infringement lawsuit after the drug is on the market. In this way, the settlement of drug patent infringement disputes is delayed until after the drug is launched, which affects the protection of drug innovation and increases the risk of patent infringement lawsuits after the release of generic drugs, which is not beneficial to both drug patentees and generic drug manufacturers.

3.2.3. The prosecution conditions for generic drug applicants to challenge patents need to be clarified or broadened. Article 18 of the Opinions on Deepening Reform and Encouraging Innovation stipulates: "A certain period of data protection shall be granted to self-acquired and undisclosed test data and other data submitted by drug registration applicants who successfully challenge patents. The data protection period is calculated from the date of drug approval. During the period of data protection, no other applicant's application for listing of the same variety shall be approved, unless the data obtained by the applicant himself or the consent of the applicant who has obtained the marketing authorization." The rules do not specify the conditions under which generic applicants can Sue to challenge patents.

4. Suggestions on improving the protection of the patent link system in China

4.1. Simplify the drug marketing examination and approval procedures

Drug patent system is closely related to drug authorization procedure. Improving and simplifying new drug application procedure is the premise of establishing drug patent linkage system. The development of innovative drugs is difficult, time-consuming, and risky, and the process for bringing innovative drugs to market is relatively complex, requiring preclinical and clinical trial studies in human subjects (phase I, II, III, and IV) to demonstrate the safety and efficacy of the drug, as well as the safety and efficacy of appropriate data. Innovative drugs are a prerequisite for the reproduction and sale of generic drugs, and the development of generic drugs is related to innovative drugs. If generics are subject to the same rigorous approval process as innovative drugs, this will increase their cost and delay their arrival on the market. Therefore, the system design needs to do a good job in two aspects. The first is optimizing the approval process of innovative drugs and accelerating the review and approval of innovative drugs. The second is scientifically simplifying the approval process of generic drugs and shortening the time of access. Only by simplifying access procedures, improving review efficiency and shortening access times can we ensure that innovative and generic medicines are on the market in a timely manner, effectively reduce waiting times and improve public access to medicines.

4.2. Revise and improve procedures for invalidation of drug patents

According to the operation principle of drug patent link system, the result of patent infringement lawsuit directly affects the sales of generic drugs. This requires the court to improve the efficiency of patent infringement litigation. In the U.S. patent system, there are two ways to determine the validity of patent law: one is through administrative process, the other is through judicial process. Considering the complexity of technical and legal issues in patent technology cases involving the interaction of civil actions. Administrative disputes over patent invalidity and patent infringement should be handled in a

unified manner, and centralized jurisdiction of technology patent cases should be realized, and specific disputes should be handled by special intellectual property courts to improve hearing efficiency and professionalism.

5. Conclusion

Drug patent link system plays an important role in balancing the interests between innovation and generic drugs enterprise. In the process of building the system in China, it is important to pay special attention to the localization development. On the one hand, the establishment of the system should adapt to the development status of Chinese pharmaceutical enterprises and stimulate the vitality of the pharmaceutical market. On the other hand, t is necessary to balance the interests of all parties to maximize national interests.

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