ISSN 2706-6827 Vol. 7, Issue 1: 12-18, DOI: 10.25236/IJFS.2025.070103

Research on drug patent linkage system

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Abstract: *This paper first summarizes the development process and main contents of China's drug patent linkage system, including the patent information registration and publicity system, the simplified application system for generic drugs, the patent exemption system and the monopoly period system for the first generic drug market. Subsequently, this paper analyzes the shortcomings of the system, such as the optimization of the drug patent registration platform, the reasonable setting of the waiting period, and the dispute resolution mechanism of the dual-track administrative and judicial system. Finally, this paper puts forward some suggestions for improving the drug patent linkage system in China, including improving the information registration and publicity platform, standardizing the application procedures for drug patent declarations, and reasonably setting the waiting period for chemical drugs.*

Keywords: *drug patent linkage system, generic drugs, patent information registration, dispute resolution mechanism*

1. Overview of China's drug patent linkage system

1.1. The development process of China's drug patent linkage system

The development process of China's drug patent linkage system can be traced back to the Drug Registration Regulations of 2002, which stipulates that the examination authority shall disclose information on pharmaceutical products, and the applicant shall make relevant explanations and general licenses, and the generic manufacturers shall conduct prior authorization. However, the above-mentioned provisions only mention the explanatory part, which has not been confirmed in the whole, and there are no specific implementation provisions, so China's drug patent chain system has remained at the theoretical level for a long time. Secondly, the reform of the drug evaluation system in 2105 in China has promoted and promoted the development of the system. The Several Opinions on the Quality and Effectiveness Assessment of Generic Drug Products (2016) stipulates for the first time that generic drug manufacturers must use APIs to ensure their bioequivalence to ensure their product quality and effectiveness. In this clause, it is considered as a basis in the market. In May 2017, the "Relevant Policies on Supporting the Innovation of New Drugs and Medical Devices and Protecting the Rights and Interests of Innovators (Draft for Comments)" clearly proposed for the first time the establishment of a patent linkage system to stimulate technological innovation and development. Subsequently, the "Several Opinions on Promoting the Reform of the Review and Approval System to Support the Innovation of New Drug Medical Instrument Technology" was issued in May 2017, and in addition, the state further issued the "Opinions on Strengthening the Protection of Intellectual Property Rights" (2019), indicating that China has strengthened the establishment of a new drug patent linkage system. In January 2020, the China-US Economic and Trade Agreement clearly pointed out the establishment of a linkage management system for drug invention patents, and to this end, the China Drug Administration and the State Intellectual Property Office jointly formulated the Implementation Measures for the Early Handling Management Mechanism of Drug Invention Patent Disputes (Trial) to standardize the registration of drug invention patents and product patent claims in a more comprehensive manner, in order to better protect the rights and interests of consumers themselves[1]. In October 2020, the Invention Patent Law was amended four times, adding a new Article 76 to provide that in the process of review and approval of drug issuance, the applicant for issuance approval may negotiate with the patentee or interested party to handle the invention patent dispute through judicial or administrative procedures, so as to safeguard the legitimate rights and interests of both parties. This marks the first formal establishment of the system in China, which is a major progress and breakthrough and has historical significance for the pharmaceutical industry. On July 5, 2021, Article 76 of the Patent Law came into effect, and the Supreme People's Court and the central competent authorities formulated applicable laws and regulations on specific issues after in-depth consultations to protect the legitimate rights and interests of citizens. Requirements of the

ISSN 2706-6827 Vol. 7, Issue 1: 12-18, DOI: 10.25236/IJFS.2025.070103

Supreme People's Court on Drug Registration in Civil Cases of Patent Disputes. The judicial interpretation of the court's protection, preservation, restitution of trade secrets, and the right to fair trial matters, provides clear guidance in a timely manner, and promotes the implementation of the drug patent linkage system.[2]

1.2. The main content of China's drug patent links

China's drug patent linkage system consists of a patent information registration and publicity system, and a simplified application system for generic drugs, including patent declaration, approval waiting period, patent exemption system, and market exclusivity period system after successful patent challenge. Drug patent registration and publicity system. On July 4, 2021, the National Medical Products Administration (NMPA) and the State Intellectual Property Office (CNIPA) issued the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) (hereinafter referred to as the "Implementation Measures") Article 2.11 stipulates the establishment of a patent information registration platform for marketed drugs in China. The purpose of the drug patent information registration and publicity system is to publicize the relevant information of the original drug, and the generic drug can check the patent information of the generic drug in advance to avoid infringement of the rights of the original drug. China's Orange Book can be traced back to the 2017 China Listed Drugs List, which contains information on drugs approved for marketing by the China Food and Drug Administration, which is publicly available to the public and updated in real time. The release of the "Implementation Method": In order to better manage drug invention patents, the state will build a "national drug invention patent data record network platform", based on the "Drug Directory", establish a drug invention patent registration network platform, in order to better resolve drug invention patent disputes, and clarify the responsibilities and obligations of applicants. Simplify the generic drug declaration system. In March 2020, China revised the Measures for the Administration of Drug Registration, and Article 35 of the amendment stipulates that generic drugs can be directly marketed without carrying out drug clinical trials after being evaluated by the applicant. The simplified application system for generic drugs mainly includes: patent declaration system and waiting period. The drug patent declaration refers to the fact that before applying for marketing, generic drugs must submit a description of the patent status and ownership status to the national drug evaluation agency and the patentee of the drug for the drug that has been declared for registration[3]. The patent declaration system is essentially a way of publicity and notification, and it is a bridge between the approval of original drugs and generic drugs. On the other hand, it also speeds up the application process for generic drugs. China's "Implementation Measures" stipulate the content of drug patent declarations. Generic drug registration applicants can submit four types of declarations through China's listed drug patent information registration platform: the first type of declaration is that there is no relevant drug patent information content on the drug catalog; The second type of declaration is that even if there is information about the drug, the term of the patent has expired or has been invalidated by the court; The third category is to state that the generic drug will not be marketed within the valid patent period of the original drug, and the fourth category is the patent challenge mentioned above, and the generic drug on the market will not cause any infringement. According to this requirement, the applicant for generic drug registration shall expand and explain all the relevant information about the patent of the original drug, but the statement is published on the website of the drug regulatory authority. If the relevant drug patentee does not pay attention to it at all times, it will be difficult to see the relevant statement of the generic drug registration applicant, which will easily cause subsequent patent disputes. The waiting period is to give the original drug company and the generic drug company a certain amount of time to wait for the court's decision, so that the market time of the generic drug has more accurate legal predictability. The length of the waiting period must be set to fully consider the time of prosecution, approval and other processes, and balance the harm of the delay in the launch of generic drugs to both parties and the counterfeiters. If the waiting period is too long, it will undoubtedly affect the market share of generic drugs. For example, in extreme cases, when the waiting period expires, if the patent in question appears to be invalid or will be invalidated, it will cause a delay in the marketing time of generic drugs, and the purpose of the original design of the system will not be achieved. If the waiting period is set too short, it is likely that a large number of generic drugs will be approved for marketing without a court decision, and the generic drug company will also face the risk of being sued for infringement by the original drug company. According to China's "Implementation Measures", if there is a dispute between the relevant rights holders or interested parties of the generic drug applicant over the patent declaration or the law on which the declaration is based, they may file a lawsuit with the people's court within 45 days of the publication of the generic drug license application or file an administrative arbitration with the patent department of the State Council to protect their own rights and interests[4]. The length of the waiting period in China is generally set at 9 months. The patent

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exemption system is not found to be an infringement after administrative review. In this way, generic drug companies can produce within the validity period of the patent to ensure that the low-cost generic drug or medical device can be put on the market as soon as possible when the relevant drug patent expires. This is because during the validity period of the patent, engaging in experimental activities to provide the data and information required for the administrative license will not undermine the dominant position of the drug patentee in the market, nor will it unduly interfere with the normal exercise of the patentee's intellectual property rights. Paragraph 5 of Article 75 of the Patent Law of the People's Republic of China stipulates that acts involving the original drug that is still within the patent protection period due to the above-mentioned reasons shall not be regarded as patent infringement. China's drug patent infringement exemption is similar to the "Bolar" exception in the United States, but it is different from that of the United States. At present, there is no relevant legal provision on fictitious infringement in China. In the author's opinion, the provisions of "fictitious infringement" and the Patent Law have been amended, so encouraging intellectual property owners to file patent infringement lawsuits would violate the basic principles and legal spirit of the Legislation Law[5]. In addition, if the "fictitious infringement" and the Patent Law were amended without the approval of the national legislature, the enforcement of the law would be adversely affected. However, in fact, the fictitious infringement system is a necessary part of the supporting system for drug patent protection, and its core is to shorten the time for the registration and approval of generic drugs and facilitate the listing of generic drugs. The monopoly period system in the first generic drug market refers to the system in which the generic drug is first applied to the drug review agency for marketing, and at the same time the original drug patent challenge is applied, and an opposition is raised after the application is successful. Generic drugs will enjoy a longer market monopoly. During this period, there were only original drugs and generic drugs on the market. The system will play a key role in enabling generic drug manufacturers to take the initiative to challenge patents, promote the rapid launch of generic drugs, reduce drug prices, and balance the rights and interests of original and generic drugs. According to Article 11 of China's Implementation Measures, the NMPA will grant a 12-month monopoly period for the first generic drug to challenge the invention patent, during which time no other generic drugs will be approved for distribution. In addition, it is also emphasized that the 12-month market monopoly period cannot exceed the patent validity period of the challenged drug. The NMPA will continue to conduct technical reviews of other generic drugs within 12 months to ensure that their quality meets standards. If other generic drugs of the same type pass the technical review during this period, the generic drug can be transferred to the administrative approval stage 20 working days before the expiration of the market exclusivity period of the generic drug that has successfully challenged. Compared with the exclusive period of the first generic drug in the United States, China gives generic drug companies a longer market monopoly period. At this stage, China's independent innovation drug research and development cycle is slow, independent innovation ability is insufficient, coupled with China's large population, there is an urgent shortage of a large number of generic drugs to improve the public's accessibility to drugs[6]. Therefore, the 12-month exclusivity period of the first generic drug market in China is very reasonable and effective.

2. The existing problems of China's drug patent linkage system

China's drug patent linkage system can play a role in regulating the defects of the pharmaceutical market mechanism for the research and development, classification, patent approval and registration of new drugs, and the design of the 9-month waiting period. However, the state administrative department is faced with the following problems in dealing with the registration of drug patent information in the application for drug marketing authorization, and the court is faced with the following problems in dealing with patent infringement related to drug patent registration.

2.1. Optimization of drug patent registration platform

Through the establishment of a patent information registration platform, it is not only necessary to fully cover drug patents, but also to provide a solid data foundation for the establishment of a system. However, there are also imperfect registration information classification systems and lack of drug patent publication information, as follows: the registration information classification system is not perfect. On the drug information registration platform, there is no classification of drug patent information, and relevant stakeholders cannot easily consult it. The grant of a marketing authorization, whether a new drug or a generic, requires the marketing authorization applicant to state the patent status and infringement. The registration of new drug patent information is a prerequisite for the normal operation of the drug patent linkage system. These legal statuses are closely related to the success of applying for

ISSN 2706-6827 Vol. 7, Issue 1: 12-18, DOI: 10.25236/IJFS.2025.070103

marketing authorization for generic drugs[7]. At present, the Chinese patent information registration materials registered on the platform clearly stipulate that the registration certificate must be obtained within 30 days for patented drugs, but the drug registration management information is not perfect, and the department has no right to effectively supervise the necessary drug patent information and drug registration with the patent registry. When the drug-related information is recorded or recorded correctly, the patent holder and relevant personnel have the right to make administrative decisions and resolve disputes directly in accordance with the regular procedures[8]. Therefore, even if both the original drug and the generic drug have completed the prescribed actions in accordance with the Implementation Measures, the early resolution mechanism for patent disputes cannot be initiated. In other words, both the original drug marketing authorization holder and the generic drug applicant have carried out drug patent information registration and patent declaration in accordance with the requirements of the Implementation Measures, but there are contradictions, resulting in the failure of the early resolution mechanism for drug patent disputes.

2.2. The waiting period is set reasonably

If the patentee or interested party has any objection to the patent declaration or the basis of the declaration, it may, within 45 days from the date of the announcement of the marketing authorization application by the national drug evaluation agency, file a lawsuit with the people's court on whether the relevant technical solution of the drug applied for marketing falls within the scope of protection of the relevant patent right, or apply to the patent administration department of the State Council for an administrative ruling (corresponding to the "patentee may file a patent infringement lawsuit within 45 days after obtaining the notice from the generic drug manufacturer" in the US Orange Book). From the date on which the case is filed or accepted by the people's court or the patent administration department of the State Council, the drug regulatory department of the State Council shall set a waiting period of 9 months for the registration application of chemical generic drugs, and the national drug evaluation agency shall not stop the technical review during the waiting period. However, if the patent dispute has already been filed, and then the request for administrative adjudication is made, the state administrative department will not accept it[9]. Although China stipulates a 45-day objection period and a 9-month waiting period, there are still big problems in the actual application process. Although China's Civil Procedure Law and Administrative Procedure Law stipulate that the trial of first-instance cases should be completed within 6 months, and the second-instance cases should generally be completed within 3 months, considering the complexity of patent infringement cases themselves, coupled with the mediation and technical appraisal time of specific cases, the 9-month waiting period is basically unable to meet the trial of the case, so the waiting period should be greater than 9 months.

2.3. The issue of the dispute resolution mechanism of the dual-track administrative and judicial system

The dual dispute resolution mechanism operates at both the administrative and judicial levels, and the contradictions between administrative and judicial decisions are naturally affected first by the potential for conflict. On the one hand, the dual-track system of dispute resolution is prone to the consequences of circular litigation. Administrative rulings in China are usually not final, and pharmaceutical companies usually rely on judicial procedures to resolve disputes. The Measures for Administrative Adjudication of the Mechanism for Early Settlement of Pharmaceutical Patent Disputes promulgated by the State Intellectual Property Office also stipulate that the administrative adjudication of pharmaceutical patent disputes in China does not have final effect[10]. On the other hand, it is easy to create a conflict between administrative rulings and judicial decisions. For example, the Supreme People's Court pointed out in the retrial judgment of the Jiangsu Institute of Microbiology v. Fuzhou Neptunus Pharmaceutical Co., Ltd. et al. that the Liaoning Provincial Intellectual Property Office still accepts the patent owner's request for a patent administrative adjudication even though the Haikou Intermediate People's Court has already filed a case against the relevant patent infringement dispute, which may lead to a conflict between the outcome of the civil infringement case and the outcome of the administrative case. Although the administrative case filing procedure requires that the patent dispute in the process of drug approval is not filed, in the actual application of the drug patent linkage system, there may still be cases in which both are filed at the same time.

3. Suggestions for improving China's drug patent linkage system

Although the Patent Law has established a drug patent linkage system in China and has been

ISSN 2706-6827 Vol. 7, Issue 1: 12-18, DOI: 10.25236/IJFS.2025.070103

implemented for a period of time, there are still many problems in the system itself and its practical application. The drug patent linkage system should be continuously adjusted according to the actual situation. This chapter is based on the current situation in China, and combines several suggestions on improving the drug patent linkage system in China. This includes improving the drug patent registration system, introducing fictitious infringement, reasonably setting the length of the waiting period, and strengthening the connection of functions between departments.

3.1. Complete information registration and publicity platforms

First of all, adhere to the principle of formal examination and optimize the design of the registration system. According to Article 10 of the Measures for the Administration of Drug Registration, the authority of China's drug regulatory department is to review the "safety, effectiveness and quality controllability" of drugs, especially to conduct a comprehensive substantive review of drug patent information on the registration platform. However, it is undeniable that the substantive review will greatly restrict the efficiency of China's drug registration information, which is inconsistent with the original intention of the design of the drug patent linkage system, and cannot meet the needs of encouraging the timely listing of generic drugs that meet the requirements and ensuring the possibility of national drug use. Therefore, China's information registration and publicity platform should adhere to the principle of formal review and optimize the design of the registration system to achieve timely and accurate registration of relevant information of drugs[11]. Second, establish a regulatory mechanism for information registration platforms. The drug regulatory authority is not a qualified "gatekeeper" to prevent improper patent registration, because it does not have the legal authority, resources and professional knowledge and skills to identify the authenticity, accuracy and completeness of drug patent information. Historical experience tells us that any system without a regulatory mechanism will eventually be reduced to mere rhetoric or even into a state of chaos. Although the drug regulatory department is not a suitable "gatekeeper", as the frontline soldier of the drug patent linkage system, it can modify or delete inappropriate patent registration information when it conducts formal or substantive examination. In addition, in order to better build an information registration platform, the drug regulatory department and the patent administration department should establish a functional convergence, and the two should rely on each other and share information resources. Finally, the opposition procedure for the construction of improper registration. The drug patent linkage system in the United States and South Korea has set up opposition procedures for improper registration of information registration platforms, and based on past experience, China should also set up such procedures to balance the interests of all parties. Administrative objections to improper registration of patent information of marketed drugs in China can be divided into two parts: self-negotiation and administrative review. First of all, the drug regulatory department only acts as an intermediary for information transmission, and anyone who has any objection to the drug patent information published on the registration platform can submit an objection application to the drug regulatory department and submit the corresponding supporting materials. The drug marketing authorization holder shall decide to delete, modify or maintain the registration of drug patent information and explain the reasons within 30 days after receiving the notice, and the drug regulatory department will transfer the decision and reasons of the marketing authorization holder to the objecting party, and if the objecting party no longer raises an objection, the opposition procedure will be terminated[12]. If the objecting party still has objections, it can apply to the drug regulatory department for administrative review of the objection, and the objection procedure enters the administrative review link, in which the drug regulatory department has the right to directly delete or modify the form error of patent information registration, and the objection involving the substantive content will be handled by the two departments of the convergence agency, which will rule on the objection, and then submit the ruling results to the drug regulatory department for implementation. Such an arrangement can promote full and effective communication between the objecting party and the marketing authorization holder, solve the problem in the negotiation stage as much as possible, reduce the occurrence of post-marketing patent disputes of drugs, and reduce costs for all parties.

3.2. Standardize the application procedures for drug patent declarations

First of all, improve the application procedures for drug patent declaration. In the "1234" statement, the applicant should elaborate on the reasons for its marketing request and provide relevant supporting materials, so that the generic drug owner and the original drug rights holder can have a more accurate and clear understanding of the drug patent information, and at the same time, it will also help to establish an effective accountability mechanism. If the applicant provides false information or other concealment during the approval process of a generic drug, resulting in the drug being approved for marketing, then

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the generic applicant should be held liable for this situation. In the process of this review, China can establish an effective linkage mechanism, as mentioned above, the State Administration for Market Regulation and the State Intellectual Property Office to establish a functional linkage system. After applying for marketing of a generic drug and submitting relevant materials, the State Administration for Market Regulation will submit the patent information of the drug to the State Intellectual Property Office and feedback to the State Administration for Market Regulation, which will be used as a reference for approving the drug to prevent the generic drug manufacturer from infringing the patent right. In addition, for patent challenges, i.e., the fourth type of application, China should stipulate that after the generic drug applicant includes a declaration of patent challenge in its application, it shall submit the patent challenge application and related material information to the patentee at the same time, and further stipulate the application period and content of the notice of dispute including the patent application for generic drugs within the validity period of the patent. After the generic drug applicant submits the patent challenge notice to the patentee of the original drug, it shall give feedback to the State Food and Drug Administration in a timely manner, indicating that it has completed the relevant procedures, otherwise, the State Administration for Market Regulation has the right not to approve the generic drug to be marketed. Second, improve the types of drug patent declarations[13]. Compared with the four types of declarations of the U.S. drug patent linkage system, the following four types of declarations should be submitted for drugs in China. Category 1 Statement: The drug patent information registration platform does not have the patent registration information of the relevant drug. The second type of statement: the patent right of the new drug or the original drug has expired or the term has expired. Category 3 Statement: The new drug or the original drug still has the patent right, but the generic drug applicant undertakes not to apply for marketing the generic drug within the patent term of the aforementioned drug. Category 4 Statement: The patent right of the new drug is invalid. In such a statement, the generic drug applicant requests the drug regulatory department to produce and sell the relevant drug before the expiration of the relevant drug patent registered on the drug patent registration information platform.

3.3. Set a reasonable waiting period for chemicals

As one of the core components of the drug patent linkage system, the approval waiting period is of great strategic significance. The trial time of civil litigation in China is generally 6 months, and the second instance is 3 months, however, in invention patent infringement lawsuits, the accused infringing unit usually files a patent invalidation procedure, in this case, the pharmaceutical technical issues involved in this case are more complicated, which brings greater pressure to the trial process. In recent years, China has actively promoted the protection of intellectual property rights, and the number of invention patent cases has increased significantly, making it extremely difficult for the competent judge to conclude patent infringement cases within nine months. In addition, it is difficult to make an administrative decision to submit for judicial review within nine months, and the goal of early resolution of patent disputes is almost impossible to achieve. According to the third paragraph of Article 9 of the Specific Practice of the Administrative Mechanism for the Early Disposal of Disputes over Pharmaceutical Invention Patents (Pilot), if the national pharmaceutical regulatory authority has not received the formal effective judgment or coordination letter from the people's court, or the administrative decision of the relevant national patent administrative authority, it shall, in accordance with the prescribed procedures, enter the registration and application of the relevant chemical generic drugs into the administrative examination and approval link to ensure its legality and effectiveness. According to the statistics of drug patent infringement litigation in the United States, the time limit for the first trial is generally 25 months, and China's practice shows that the rate of reversal of the judgment in the second instance is extremely low. In order to further develop China's drug patent linkage system, it is not appropriate to establish a long waiting period, but China can learn from the practice of the United States and establish a first-instance ruling on patent infringement or a patent management ruling as a reference basis for the marketing application of generic drugs. In addition, if a drug has more than one patent right, the patentee can file multiple lawsuits, thereby further delaying the listing time of generic drugs.

4. Conclusions

Today, the drug patent linkage system has been in operation for a year and a half. Both the patentee and the generic drug applicant exercise their respective rights and perform corresponding obligations in accordance with the aforesaid provisions, and the patentee also files a civil lawsuit and administrative adjudication request with the Beijing Intellectual Property Court and the State Intellectual Property Office for the disputed part of the declaration. On the whole, there are still major conflicts in the actual

ISSN 2706-6827 Vol. 7, Issue 1: 12-18, DOI: 10.25236/IJFS.2025.070103

handling of relevant cases. China should weigh the interests of both the original drug manufacturer and the generic drug manufacturer, and at the same time properly design control measures to reduce or avoid abusive litigation by the original drug manufacturer from the perspective of protecting the rights and interests of public health. This is the most important value to pursue. For infringement cases, in the actual handling of the case, the judicial and administrative organs may give appropriate preference to them in the course of handling, such as scheduling court sessions, but they must not contradict the concept of judicial impartiality. Patent law is a private right, whether it is a drug right holder or a generic drug company, its core is to fight for private interests, and cannot oppose the health rights of the state and citizens. The patent system in this context refers to the conversion of patent rights as trustworthy property rights into official enforcement rights by official authorities. The establishment of the pharmaceutical patent system itself is a political tendency of private law, which has become a special treatment for the public power of the state, which in turn damages the procedural rights of other types of cases and lacks sufficient rationality. The goal of the system is to connect drug patents and installation through the system, on the one hand, actively guide, encourage and encourage Chinese pharmaceutical companies to actively innovate, change the long-term situation of innovative drugs in the foreign drug patent market, and in order to protect the life and health of the country, consumers can buy more effective drugs at lower prices.

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