Anti-Monopoly Regulation and Improvement of Reverse Payment Agreements in Drug Patent Rights

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Abstract: Following the implementation of China's drug patent linkage system, reverse payment agreements have proliferated in the pharmaceutical sector. While streamlining patent dispute resolutions, these agreements risk suppressing market competition and undermining public health. Analysis identifies structural deficiencies in China's legal framework, including ambiguous re-view criteria, fragmented regulatory systems. The system fails to reconcile patent protection with antitrust objectives, as evidenced by the 2021 landmark case revealing imbalances in bur-den of proof and legal interpretation. To address these challenges, three reforms are proposed: a tiered review framework to categorize agreements based on risk, mandatory patent registration coupled with dynamic quantitative evaluation mechanisms, and enhanced scrutiny of non-monetary compensation and robust public interest litigation. The study emphasizes dismantling the "zero-sum game" between patent monopolies and public health through adaptive legislation, risk early-warning systems, and multi-stakeholder governance. These measures aim to incentivize pharmaceutical innovation while safeguarding public welfare, ensuring sustainable industry development.

1 INTRODUCTION

In the process of vigorous development of the pharmaceutical industry, the reverse payment agreement in drug patent rights has gradually become a focus of attention inside and outside the industry. With the implementation of the drug patent linkage system in China, the frequency of this special agreement in China has increased significantly. The so-called reverse payment agreement refers to a special settlement agreement reached between the original drug company and the generic drug company in the course of a patent dispute. In the agreement, the original drug company will pay a certain benefit to the generic drug company in exchange for the generic drug company delaying its entry into the market or giving up the promise to challenge the patent.

From a market competition perspective, the impact of reverse payment protocols is complex. On the one hand, the original pharmaceutical companies have maintained their monopoly position in the drug market in the short term by delaying the entry of generic drugs into the market by paying benefits, but it may also inhibit the competitive vitality of the market and reduce the choice space of consumers. On the other hand, such an agreement may also provide certain financial support for the original pharmaceutical company, so that it can have more resources to invest in the research and development of new drugs, which may promote the innovation and development of the pharmaceutical industry in the long run. From the perspective of public health, the price of original drugs is often high, and the timely listing of generic drugs can increase market supply, reduce drug prices, improve the accessibility of drugs, and benefit more patients. However, if a reverse payment agreement delays the entry of generic drugs into the market, patients may have to bear high drug prices for a period of time, which will undoubtedly hurt public health interests.

From this point of view, it is of great practical significance to study the anti-monopoly regulation of reverse payment agreements in drug patent rights, which is not only related to the maintenance of market competition order in the pharmaceutical industry, but also directly affects the health rights and interests of the public and the sustainable development of the entire pharmaceutical industry. Through reasonable anti-monopoly regulations, we can ensure the fairness and effectiveness of market competition while

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protecting patent rights, and then promote the development of the pharmaceutical industry in the direction of innovation and health.

Based on the Chinese context, this paper takes the first reverse payment agreement case as the starting point, constructs a "stepped examination framework" and a dynamic quantitative evaluation model, innovatively introduces the game theory of "separation equilibrium" to identify weak patent signals, proposes a linkage mechanism between public interest litigation and risk early warning, solves the problem of regulatory failure, balances patent protection and public health, and provides Chinese solutions for global pharmaceutical anti-monopoly.

2 ANTI-MONOPOLY REGULATION OF REVERSE PAYMENT AGREEMENTS

2.1 The Inherent Contradictions of the Review Rules and the Extraterritorial Experience

The United States has carried out a series of explorations and practices in the review rules of reverse payment protocols, and has tried a variety of rules, but there are different degrees of defects in them. The advantage of this type of rule is that it is efficient and clear, and can quickly and effectively regulate some agreements that obviously restrict competition, but its disadvantages are also obvious, and it may ignore the pro-competition effect of some agreements in general. In practice, the validity of a patent is not absolute, and there may be disputes and uncertainties, and the definition of patent scope is often vague, and there are differences between different subjects, which makes it difficult to predict the results of the examination according to the rules, making it impossible for enterprises to accurately judge the legality of their own actions when signing an agreement. The purpose of the expedited review rule is to improve the efficiency of the review, but the frequency of application in practice is low, mainly because of its predictability and compatibility, and it is difficult for enterprises to grasp the specific application standards of the rule in practice, resulting in their inability to effectively prepare relevant materials and make reasonable defenses in the face of agreement review, and at the same time, the rule is prone to rule conflicts in the actual operation process, and the compatibility with other laws and regulations needs to be improved. Reasonable rules comprehensively consider a variety of factors, including the impact of the agreement on market competition, the market position of the enterprise, the purpose and effect of the agreement, etc., this kind of rule is a bit to be able to evaluate the legitimacy of the agreement more comprehensively and objectively, but its disadvantage is that it is flexible, the standards are different, and the judge's weight judgment of various factors may be different in different cases, which leads to the uncertainty of the review result, and because of the comprehensive consideration of many factors, the litigation process is often delayed. As a result, the litigation cost and time cost of enterprises have greatly increased (Xiao, 2023).

At present, China has not formed a clear and unified standard for the review rules of reverse payment agreements, and there is a conflict between legislation and justice. From a legislative perspective, Article 12 of the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (hereinafter referred to as the "Drug Measures") stipulates that "the parties shall not exclude or restrict the marketing of generic drugs through agreements", reflecting the strict stance of adopting "inherently illegal rules" for reverse payment agreements (Ge and Wang, 2023). However, in judicial practice, in the first reverse payment agreement case (2021) Zui Gao Fa Zhi Min Zhong No. 388, "reasonable rules" were adopted for review, resulting in a contradictory situation of "strict legislation and lax justice".

In this case, the Supreme People's Court found that the Settlement Agreement in question met the appearance characteristics of a "reverse payment agreement for a drug patent", and pointed out that "such an agreement may constitute a monopolistic act, and its impact on market competition needs to be analyzed in light of the specific circumstances". However, the court ultimately allowed AstraZeneca to withdraw its appeal on the grounds that "the patent in question has expired" and "there is no direct evidence to prove monopoly damage". This judgment also exposed multiple problems: (1) the ambiguity of the review criteria: although the court recognized the potential illegality of the reverse payment agreement, it did not clearly define the criteria for determining "monopoly damage", and only avoided substantive examination on the grounds that the patent expired; (2) Imbalance in the burden of proof: According to Article 8 of the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Monopoly Dispute Cases, the plaintiff needs to prove that the defendant has a

dominant market position and abuse, but in this case, the generic drug company does not need to prove the legitimacy of the agreement, resulting in a virtual burden of proof system; (3) Contradictions in the application of law: There is a tension between the "per se illegality" tendency of the Drug Measures and the "exemption clause" in Article 15 of the AML, and the judicial authorities tend to choose reasonable rules that are more lenient towards pharmaceutical companies in individual cases (Supreme People's Court of China, 2021; Ouyang, 2023).

2.2 The Fragmentation of Legal Regulation and the Need for Institutional Reconstruction

Although China's patent linkage system has been initially established, there are still many areas that need to be improved. For example, in the case of patent registration, a series of problems may arise in the process of changing from self-registration to compulsory registration. On the one hand, mandatory registration may increase the burden on enterprises, leading some enterprises to take some improper actions in order to avoid registration. On the other hand, if there is no effective supervision of the registration process, improper registration may also occur, which may lead to the formation of illegal patent monopolies and the creation of more reverse payment agreements. The provisions on joint patent challenges in China are also not clear enough, and the scope of challengers has not been clearly defined, which makes it difficult for generic drug companies to face many uncertainties when challenging patents, making it difficult to effectively play the deterrent effect of joint patent challenges on original pharmaceutical companies, and to achieve the expected effect of reducing the occurrence of reverse payment agreements (Xiao, 2023).

In addition, in China's current legal system, there are overlaps and gaps in the regulation of reverse payment agreements in the Anti-Monopoly Law, the Patent Law and the Drug Administration Law. Article 17 of the Anti-Monopoly Law prohibits abuse of a dominant market position, but it is not clear whether reverse payment constitutes "abuse"; However, Article 10 of the Implementation Measures for the Early Settlement Mechanism of Drug Patent Disputes requires generic drug companies to submit a declaration of non-infringement, but does not stipulate penalties for false declarations, resulting in the original drug company inducing generic drug companies to withdraw their legal challenges through reverse payment.

For example, in the (2021) Supreme Court Zhi Min Zhong No. 388 case, the settlement agreement signed by AstraZeneca and Vcare was not found to be illegal due to the expiration of the patent, but the case exposed the passivity of judicial review - the court avoided substantive review of the agreement on the grounds of "lack of evidence", which is in stark contrast to the "In re Lipitor" case in the United States, which required the original pharmaceutical company to prove that the payment amount was reasonably related to the litigation costs, otherwise it would be directly presumed to be illegal.

2.3 Regulatory Failures Caused by the Concealment of the Agreement

The concealment of reverse payment agreements poses a serious challenge to their antitrust review, and these agreements often adopt complex transaction structures and diversified payment forms to conceal their anti-competitive nature. For example, under the guise of technology cross-licensing, the original drug company and the generic drug company ostensibly grant each other the right to use the technology, but in fact, the original drug company may pay high profits to the generic drug company in disguised form through the hidden terms in the technology license, in exchange for the delay in the generic drug company's entry into the market. In such cases, it would be difficult for the review body to discern the essence of the reverse payment from what appears to be a normal technical cooperation agreement.

In addition, some enterprises use the OEM business to implement reverse payment, and the original pharmaceutical company entrusts the production task of some drugs to the generic drug company, sets unreasonably high processing fees in the OEM contract, or gives the generic drug company "quality rewards" far beyond the normal level of the market, etc., these additional costs are actually a form of reverse payment. As the co-packing business is a common business model in the pharmaceutical industry, it is difficult to distinguish whether these fees are normal commercial transaction prices or reverse payment means.

Reverse payments through investment are also increasing, and the original drug company invests in generic drug companies, which seems to be a normal commercial investment behavior, but there may be a proviso in the investment agreement, requiring the generic drug company not to challenge the patent or delay the launch of the generic drug for a certain period of time. This combination of investment and reverse payment not only makes the flow of funds

more complex and hidden, but also makes the review more difficult (Li, 2023).

From the perspective of game theory, the game between original pharmaceutical companies and generic drug companies can be modeled as a dynamic game with incomplete information. If generic drug companies accept payment, a "segregated equilibrium" is formed — that is, weak patent companies tend to pay to cover up patent invalidity, and regulators need to break this equilibrium by enhancing information transparency (Shapirp, 2003).

3 SUGGESTIONS FOR IMPROVING THE ANTI-MONOPOLY REGULATION OF REVERSE PAYMENT AGREEMENTS

3.1 Clarify the Rules of Review

China should take into account its own actual situation and build a scientific and rational system of review rules. In terms of drawing on international experience, we can refer to the advantages of the EU classification regulatory model, especially the "dynamic market share threshold" review method emphasized by the European Commission in the latest interpretation of the Lundbeck case in recent years, and at the same time optimize the fast-track review rules (Federico et al, 2023). Based on key indicators such as patent validity, competition restrictions, and payment scale, the classification is carried out in a tiered manner. For reverse payment agreements with high patent validity, low degree of competition restriction and small payment scale, a relatively simplified examination process can be applied; Agreements with questionable patent validity, obvious competition restrictions, and large payment scales are subject to stricter scrutiny.

When establishing the event tree analysis method, it is necessary to clarify the criteria for determining the competitive effect of the agreement, start from the background and purpose of the agreement, and gradually examine the impact of the agreement on the market structure, consumer welfare, and industry innovation, and at the same time give both parties equal rights to defend and reasonably allocate the burden of proof (Xiao, 2023). For example, if the patent has obvious flaws, then the reverse payment agreement based on the patent should be examined, and then the degree of restriction of the agreement on market competition, including the impact on entry barriers and price competition in the relevant market, should be analyzed. According to the 2023 Journal of Antitrust Enforcement, the concealment of non-cash payments (e.g., technology licensing) in agreements may lead to a 20%-35% increase in market entry barriers, which can provide a reference for the quantification of China's review standards (Kwon and Kim, 2024). It is also a feasible idea to adopt the principle of "prohibition + exemption" to determine illegality, prohibiting reverse payment agreements in principle to maintain the basic order of market competition, but giving specific exemptions to those agreements that can prove to have the ability to promote innovation, improve production efficiency or other benefits to the public interest is in line with the requirements of drug innovation and development, can increase the burden of proof on the original drug companies, and correct the information asymmetry and game status imbalance between the original drug companies and generic drug companies (Ouyang, 2025).

When determining the review rules, reference may be made to the provisions of Article 2 of the Anti-Monopoly Law of the People's Republic of China on the scope of application and Article 15 of the Anti-Monopoly Law of the People's Republic of China on the exemption of agreements. The relevant provisions on monopoly agreements in the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Monopoly Dispute Cases can also provide a specific basis for the application of law for review.

3.2 Improve the Relevant Legal System

Based on the latest experience in emerging pharmaceutical markets in Asia, the mandatory registration system needs to be linked to the incentive mechanism for generic drug companies, such as giving priority to generic drug companies that successfully challenge patents for listing [Lee et al,2023]. In terms of patent registration, the compulsory registration system has been fully implemented and a strict examination mechanism has been established. Conduct a detailed review of the patent registration application submitted by the enterprise to ensure that the registration information is true, accurate and complete. Enterprises that deliberately provide false registration information or register through improper means will be subject to severe administrative penalties, including heavy fines and restrictions on market access. At the same time,

the registration process should be simplified, and an online registration platform should be established using information technology to improve registration efficiency, reduce the registration cost of enterprises, and reduce the evasion of registration caused by cumbersome procedures (Xiao, 2023)

Article 76 of the Patent Law of the People's Republic of China stipulates the relevant obligations of drug marketing authorization holders and generic drug applicants in the early resolution mechanism of drug patent disputes, which provides a legal basis for improving the patent linkage system. For the first time, the Anti-Monopoly Guidelines for the Pharmaceutical Sector (Draft for Comments) clearly stipulate the "anti-monopoly payment agreement" from the enforcement level, which can provide direction and reference for improving the relevant legal system.

Clarify the provisions on joint patent challenges and clearly define the scope of challengers. We can learn from successful international experiences, such as the incentive mechanism for patent challenges in the Hatch-Waxman Act in the United States, and formulate reasonable qualification criteria for challengers based on the actual situation in China. For example, only generic drug companies with certain R&D capabilities and technical strength are eligible to initiate joint patent challenges, which can not only ensure the quality of patent challenges, but also enhance the deterrent effect of original drug companies. The white paper on the pharmaceutical industry released by the European Union in 2022 pointed out that the enthusiasm of generic drug companies to participate in the challenge is directly related to their market share protection policies, which can provide a basis for China to design incentive mechanisms (European Commission, 2022).

3.3 Strengthen Review and Supervision

To strengthen the review of reverse payment protocols, it is necessary to establish a multi-dimensional review system. According to a 2023 study by World Competition, the concealment of reverse payment fees has shifted from a single cash payment to a hybrid form, such as technology licensing and market segmentation, so it is important to focus on the true market value of non-monetary payments (Federico et al, 2023). Accurately assess the cash value of non-monetary payment recipients when reviewing non-monetary payments in agreements. For example, for non-monetary forms of payment such as technology licensing and processing services, a professional appraisal agency or industry expert will determine the reasonable cash value based on market conditions, technical value and other factors, so as to prevent enterprises from using non-monetary payment means to evade censorship. Comparing the reverse payment costs with the litigation costs that may be incurred, if the reverse payment costs are significantly higher than the reasonable litigation costs, then it is necessary to further examine whether the agreement has an unreasonable anti-competitive purpose.

The establishment of a public interest litigation system is an important measure to strengthen supervision. According to the FTC's 2023 annual report, public interest litigation can increase the detection rate of reverse payment agreements by 40%, and China can refer to its experience to give prosecutors and relevant social organizations the right to sue in public interest (Federico et al, 2023). When reverse payment constitutes a monopoly agreement and harms the public interest, the procuratorate and social organizations can file a public interest lawsuit in accordance with the law. As a legal supervision organ, the procuratorate has professional legal knowledge and investigative capabilities, and can effectively investigate and prosecute reverse payment behaviors. Relevant social organizations, such as consumer rights protection associations and pharmaceutical industry associations, represent the interests of consumers and industry practitioners, and can promptly discover the harm caused by reverse payment to the public interest, and safeguard the order of market competition and public health rights and interests through public interest litigation.

4 CONCLUSION

The anti-monopoly regulation of pharmaceutical patent rights is a key proposition in the contemporary intellectual property legal system, and its essence lies in seeking a dynamic balance between innovation incentives and public interests. With the profound changes in the pattern of the global pharmaceutical industry, the contradiction between patent protection and market competition has become increasingly prominent. This trend not only affects the innovation and development momentum of the pharmaceutical industry, but also directly relates to the sustainable development of the public health system.

In the future, the anti-monopoly regulation of pharmaceutical patents should focus on building three mechanisms: a dynamic and balanced legislative adjustment mechanism, which responds to

technological changes through regular amendments; Accurate and efficient risk early warning mechanism, using big data to monitor changes in patent layout; A multi-participatory co-governance coordination mechanism that absorbs social forces such as industry associations and patient organizations to participate in policy formulation. Only by breaking the "zero-sum game" between patent monopoly and public health through institutional innovation can we achieve a virtuous circle of pharmaceutical innovation ecology, which not only ensures that developers get reasonable returns, but also ensures that the public can obtain life-saving drugs at affordable prices, and finally achieves the dual goals of innovation-driven and people's livelihood protection under the "Healthy China" strategy.

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