Regulating Reverse Payment Agreements in Pharmaceutical Market: A Comprehensive Framework for Antitrust Review

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Abstract. Reverse payment settlement agreement is a type of arrangement between original and generic drug manufacturers that could potentially violate Antitrust Laws by limiting competition, typically appear in the pharmaceutical market. This paper addresses the impact of these agreements on public interests, and the challenges in conducting antitrust review on these agreements. This paper then proposes a comprehensive framework for regulating reverse payment agreements in the context of China’s extensive and complex pharmaceutical market by drawing on the experiences of the United States and the European Union. The framework introduces a two-step antitrust review system for regulating patent settlement agreements, which is suggested by the author to be applied in both patent litigation and daily detection. This paper also advocates establishing an agreement filing system and utilizing the antitrust public interest litigation system in antitrust regulation. This proposed framework provides specific guidance on initiation of antitrust review with respect to multiple backgrounds, in order to protect consumer interests in affordable healthcare, deter anti-competitive behavior, and contribute to the theoretical basis for future legislation.

1. Introduction

Reverse payment settlement agreements, also referred to as “pay-for-delay agreements”, typically occur between brand-name drug manufacturers and their generic competitors. Pay-for-delay agreements oblige a party to acknowledge the patent owner's rights and delay their market entry in return for a value transfer (pecuniary or not) from the patentee [1]. Such agreements may violate Antitrust Law, as they can exclude or limit competition in the market.

According to an investigation by the Competition Enforcement Department of the European Commission, generic drugs are the primary source of price competition in the pharmaceutical market, bringing an average 50% reduction in drug prices [2], which substantially diminished the profit of original drug manufacturers but eased the financial burden on consumers. To counteract this impact, original drug manufacturers adapt various strategies to prolong the commercial life of their original drugs. Signing reverse payment agreements with generic drug manufacturers is one of such strategies. Reverse payment agreements are a win-win for businesses, with drug prices remaining high and original drug manufacturers sharing monopoly profits with generic drug manufacturers. However, the cost to manufacturers maintaining monopoly profits is that consumers lose the opportunity to enjoy generic drugs that might be 90% cheaper than the original drug prices. It is estimated that reverse payment agreements are causing loss of $3.5 billion for American consumers every year [3]. Drugs are unique commodities with low price elasticity of demand, and consumers often lack the leverage to reject unreasonably high prices due to their health and life needs. Data shows that in 2021, chemical generic drugs accounted for 83.66% of China's chemical drug market share and 52.80% of the overall pharmaceutical market share [4]. Obviously, China is a significant producer and consumer of generic drugs. Given the vast scale of China's pharmaceutical market, allowing drug manufacturers to maintain unreasonably high drug prices through reverse payments will result in immeasurable damage to public interests.

In December 2021, the Supreme People’s Court of P.R.C. (SPC) decided on the patent infringement case between AstraZeneca Ltd and Jiangsu Ausicon Pharmaceutical Co., Ltd. In this case, BMS held a patent effective from August 3, 2005, to March 5, 2021, which was transferred to AstraZeneca on May 23, 2014. Vcare filed a request to invalidate the patent involved in the case in 2011. On January 4, 2012, BMS and Vcare signed a settlement agreement, specifying that Vcare withdraw the request for invalidation of the patent involved in exchange for permission for Vcare and its affiliates to implement the patent involved more than five years before the expiration of the patent rights protection period. Later, Vcare accordingly withdrew the request for patent invalidation, and its affiliate Ausicon implemented the patent involved. Subsequently, AstraZeneca, as the successor patent holder, sued Ausicon, alleging infringement of the patent involved. During the second instance, AstraZeneca...
applied to withdraw the appeal on the grounds of reaching a settlement agreement. The Supreme People's Court pointed out that the legal review of the withdrawal of the appeal mainly includes: whether the parties have engaged in actions that harm (1) national interests, (2) public interests, or (3) the lawful rights and interests of others [5].

The AstraZeneca case represents the first time the SPC has proactively reviewed a patent settlement agreement in a non-antitrust case to determine whether it may violate the Antitrust Law, marking a watershed in China's judicial practice in regulating reverse payment agreements. This case brings a question to the forefront: In patent litigation, should the court conduct an antitrust review of reverse payment agreements upon receiving a withdrawal application, and to what extent should such review be conducted? Considering reverse payment agreements' secretive and complex nature, relying on the court's proactive review mode has significant drawbacks. Although SPC believes that settlement agreements are suspected violating Antitrust Law and can be transferred to the antitrust enforcement agency, if necessary, the trend towards concealment and diversification of reverse payment agreements is leading to overlooking. This paper focuses on both court's antitrust review of settlement agreements in patent litigation and the regulation on these agreements in the whole market, addresses the challenges in initiating the antitrust review, and proposes a categorized management framework by drawing on the experience of the United States and the European Union. This framework is aimed at providing solutions for China to address the rise of reverse payment agreements and preparing a theoretical basis for future legislative improvement.

2. Analysis of Court’s Proactive Antitrust Review in Patent Litigations

2.1 Unavoidable Overlook on Anti-Competition Behaviors

In the AstraZeneca case, the court of first instance, relying on contract law and patent law, determined that Ausicon had the right to implement the patented invention according to the settlement agreement, thereby rejecting all litigation requests from AstraZeneca. This decision reflects that the Nanjing court did not even realize the underlying issues with anti-monopoly law within the settlement agreement [6]. These were only uncovered in the second instance, indicating the incidental nature of the court's review. Moreover, reverse payment agreements often appear lawful and can easily pass as patent settlement agreements through court review. In recent years, such agreements have taken more diverse forms, and the transfer of economic benefits has become more concealed. Many original drug manufacturers no longer directly pay generic drug manufacturers money but instead mask the true nature of their economic benefit transfers through various means, such as providing raw materials [7]. These conducts further reduce the likelihood of detection.

Additionally, under the principle of "no complaint, no action," the scope of the court's investigation can be pretty narrow. When pharmaceutical patent manufacturers and generic drug manufacturers sign reverse payment agreements, they usually include confidentiality clauses. Unless a dispute arises between the parties that lead to court litigation, such an agreement is unlikely to be discovered by the court. Therefore, agreements that have not led to disputes but, in reality, have excluded or limited market competition and violated Antitrust Law will fall into a blind spot in the review process. It is clear that the court's proactive review mode will inevitably overlook anti-competitive behavior. Since reverse payment agreements potentially pose significant harm, a more stringent anti-monopoly review method should be adopted. Furthermore, even if the parties to the agreement have a dispute and resort to the court, the court's maneuverability in reviewing reverse payment agreements remains highly constrained. Even if the court desires to conduct an in-depth review, the "no complaint, no action" principle may make it difficult to take practical action.

2.2 Challenges in Implementing Substantial Review

Another obstacle the court faces is the limited professional expertise, time, and resources needed to review such complex settlement agreements. Suppose the court is required to undertake an anti-monopoly review of such complex agreements independently. In that case, it will consume a substantial amount of time and resources, bringing additional burdens to the already overloaded court system. Additionally, parties may have a motive to conceal reverse payment agreements in their own interest and may selectively submit evidence. They might hide evidence that would lead the court to identify reverse payment agreements or even submit misleading evidence favorable to affirming settlement. They might exaggerate the fairness or necessity of the settlement on the one hand and underestimate the impact of reverse payment agreements on market competition on the other. These practices place the court in a state of information asymmetry when reviewing reverse payment agreements.

Furthermore, the companies' anticompetitive behaviors are becoming less obvious, which contributes to the difficulty. These behaviors include product hops, where a company introduces a slightly reformulated product to replace its current branded drug in the market, thereby thwarting an impending generic entry [8]. With companies often combine strategies to defeat competition that limits their ability to charge monopolistic prices, the court faces difficulties in implementing substantial reviews when examining reverse payment agreements. This not only increases the complexity of the review but may also affect its fairness and accuracy.

2.3 Procedural Barriers in Individual Rights

The effects of reverse payment agreements are extensive and may affect various parties such as generic drug manufacturers, original drug manufacturers, retail manufacturers, and consumers. These effects may extend
throughout the entire upstream and downstream of the industry. Parties have different demands in litigation based on different interests. For instance, consumers are more concerned with the price and diversity of drugs, whereas drug manufacturers focus more on developing their own industry. With different interests in mind, litigants will present significant variations in the evidence submitted. These differences will guide the direction and emphasis of the antitrust review, thereby influencing the examination outcome.

Given the diverse litigation interests, courts initiating antitrust reviews on reverse payment agreements in specific lawsuits will face multiple difficulties. Firstly, under the constraint of the principle of “a matter should not be judged twice”, which is also referred to as “ne bis in idem” in common law, the subsequent rights to bring a law suit of other related parties will be blocked. The impact of reverse payment agreements goes far beyond the parties involved in the case. Under the principle of "a matter should not be judged twice," the court's review can only focus on the disputes between the parties and judge within the law suit at hand, meaning the court could not reach the external issues. After a reverse payment agreement has been reviewed, it is almost impossible for consumers to bring a law suit claiming damages due to the agreement, as the court will consider the issue to have been already handled and will thus reject to deal with this agreement again. Although litigants can avoid the procedural barrier by submitting different evidence and raising different claims, the court's preexisting conclusion on previous agreements between original drug manufacturers and generic drug manufacturers will indirectly affect subsequent case trials. Changing the review results of reverse payment agreements would essentially undermine the court's judicial authority, a situation that original drug manufacturers, generic drug manufacturers, and consumers would not like to see.

The economic compensation issues related to reverse payment agreements may also become deadlocked due to the court's proactively initiated review. If the court finds a specific reverse payment agreement invalid in particular patent litigation for contradicting public interest, the actual consumers harmed will find it difficult to claim economic compensation, as the active review by the court does not explicitly identify the victimized party. However, if an antitrust review agency discovers and examines the reverse payment agreement, the manufacturers will receive administrative penalties according to Antitrust Law. Meanwhile, consumers can also claim for their rights based on the review results. In this way, the antitrust review agency's examination can simultaneously protect the public interest and individual consumer interests.

3. Comparative Approaches in Antitrust Review Initiation

3.1 United States: FTC and Private Enforcement

Since the Sherman Act, United States Antitrust Law has established a dual enforcement system, dividing the enforcement responsibility between public authorities and private parties, thereby forming two methods: public enforcement and private enforcement. Concerning public enforcement, the US review of reverse payment agreements is primarily overseen by the Federal Trade Commission (FTC). The Federal Trade Commission Act grants the FTC various powers, including investigating businesses or individuals suspected of violating antitrust or consumer protection laws, filing lawsuits in federal court or with administrative judges, and issuing orders. The FTC primarily discovers the existence of reverse payment agreements in two ways: first, by reviewing pharmaceutical manufacturers' agreement records. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires original drug manufacturers and generic drug manufacturers to file agreements relating to the production, sale, and market exclusivity of generic drugs with the FTC and the Department of Justice within 10 days of signing [9]. This provision is believed to have solved the information asymmetry between regulators and regulators, making reverse payment agreements easier to be detected, thus aiding antitrust review agencies in promptly evaluating agreements and taking further actions [10]. The private enforcement of US Antitrust Law is highly active. Thanks to the establishment of the class-action system, the plaintiff's litigation burden has been reduced, leading to a rapid growth in private enforcement cases. A wide range of victims is included by default in class-action lawsuits, leading to enormous potential compensation amounts, which strongly deter anti-competition businesses.

3.2 European Union: Categorized Management

The review of reverse payment agreements in Europe is primarily the responsibility of the Competition Directorate-General of the European Commission. The categorized management of reverse payment agreements is a highlight of EU’s approach, which clarified which types of settlements may warrant further scrutiny. This classification system mainly applies two legal standards: first, whether the agreement restricts the ability of generic drug manufacturers to sell their drugs; second, whether the agreement involves a value transfer from original drug manufacturers to generic drug manufacturers. The applied classification system is as follows in Table 1.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Limitation on generic entry</th>
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<tbody>
<tr>
<td>No</td>
<td>Category A</td>
</tr>
<tr>
<td>Yes</td>
<td>Category B.I.</td>
</tr>
<tr>
<td>Value transfer from originator to generic</td>
<td>Category B.I.</td>
</tr>
<tr>
<td>No</td>
<td>Category A</td>
</tr>
<tr>
<td>Yes</td>
<td>Category B.I.</td>
</tr>
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According to the above categorization, agreements that do not restrict generic drug manufacturers from selling their products are classified as Category A, while agreements restricting the entry of generic drugs are classified as Category B. Agreements restricting generic
drugs from entering the market are further divided into two categories: B.I. agreements, including those where the original research drug manufacturer does not transfer value to the generic drug manufacturer, and B.II agreements, including those where value is transferred from the original drug manufacturer to generic drug manufacturers.

Generally, Category A settlement agreements do not present Antitrust Law issues, as they allow generic drug manufacturers to bring their products to market immediately. B.I. settlements are similar, but some settlement agreements in this category may be subject to competition law scrutiny, such as settlements reached with patents known not to meet patentability standards, i.e., flawed patents, granted under circumstances where incorrect, misleading, or incomplete information was provided. This situation could still lead to an antitrust review. By contrast, B.II. settlement agreements may be subject to the most rigorous antitrust scrutiny, as they restrict market entry and include value transfer from original research drug manufacturers to non-patented drug manufacturers [11].

Furthermore, within the block exemption system, the EU introduced the concept of "core restrictions" to cover serious restrictive agreements. Legality cannot be assumed without specific scrutiny for these agreements, meaning they cannot be subject to block exemption but must be thoroughly examined according to exemption conditions. If these conditions are met, they may still be lawful. Under the block exemption system, for agreements outside the core restrictions, legality can be recognized without further consideration as long as they do not have the appearance specified in law to simplify the review process as much as possible; for agreements with core restrictions, detailed scrutiny must be conducted regardless of whether they possess the listed appearance features [12]. The EU's block exemption system has dramatically enhanced the efficiency of antitrust review. However, as reverse payment agreements become increasingly complex and concealed, and pharmaceutical manufacturers may take evasive measures against the appearance features listed in the law, the question remains whether the existing block exemption system can still accurately and comprehensively identify potential reverse payment agreements.

3.3 United Kingdom, France, and Germany: Consumer Associations as Viable Entities for Antitrust Public Interest Litigation

Consumer associations as effective organizer for consumers in antitrust claims, have been legally accepted as subjects for antitrust public interest litigation in many jurisdictions. Germany's 1965 “Act against Unfair Competition” granted consumer groups the right to bring collective lawsuits. The 8th Amendment to Germany's "Act of Restrictions on Competition" in 2013 also gave consumer groups the right to sue for inaction, exclusion, and confiscation against monopolistic behavior, forming a consumer group litigation system coordinated with the "Act against Unfair Competition." The UK's 1998 “Competition Act” Section 47B provided a consumer lawsuit request system applicable to antitrust damages and other remedies. According to this provision, consumer groups that meet the neutral, representative of consumer interests, litigation capacity, no trading department, etc., conditions specified by the Secretary of State may sue competition violators in court. France's 1973 "Loi Royer" Article 46 also allows consumer associations to sue in any court for facts that directly or indirectly harm the collective interests of consumers [13].

3.4 Insights from Comparative Perspectives of Regulating Reverse Payment Agreements

The dual enforcement system in the United States, especially active private enforcement, has reference significance for constructing our country's reverse payment agreement antitrust review system. As a developing and populous country with a vast consumer market and a significant producer and user of generic drugs, China is an easy target for foreign innovative pharmaceutical manufacturers' reverse payment agreements. Therefore, strengthening antitrust reviews to protect consumer interests is particularly important. The US and EU experience shows that neither private enforcement nor public enforcement can monopolize the execution of competition law; they must cooperate to achieve the purpose of deterring, investigating, punishing, and compensating the victims of anti-competitive behavior.

Relying solely on public or private enforcement is undesirable. Enforcement of Antitrust Law requires cooperation of public and private enforcement to achieve the best implementation effect. Public agencies' human and material resources are always limited. Private individuals with direct economic interests and consumer associations can mitigate the government's deficiencies in workforce and financial resources, supervise the law enforcement agencies, and help increasing the likelihood of discovering illegal monopolies [14].

A common point in the US and EU regulations on reverse payment agreements is the agreement filing system. Requiring manufacturers to file related agreements with antitrust review agencies when they are reached can effectively improve review efficiency. Moreover, the EU's classification management and exemption system also have reference value. Listing the surface features of agreements and exempting some agreements with a shallow risk of restricting competition also helps achieve maximum efficiency.

4. Institutional Design for Antitrust Review of Reverse Payment Agreements

4.1 Introducing Categorized Management System

In the above analysis, the author found that the court's proactive initiation of an antitrust review of reverse
payment agreements can cause many difficulties in patent litigation. The antitrust review agency also needs an effective classification system to improve the efficiency of managing recorded agreements. To avoid overburdening the courts while ensuring the litigation rights of relevant parties when dealing with withdrawal applications, introducing an a classification management system could be a practical choice. By listing the appearance of the agreement, courts, and antitrust review agencies can more easily identify the risk level of reverse payment agreements and thereby make decisions on whether to allow withdrawal or conduct different level of antitrust review on the recorded agreements. However, by simply listing appearances elements the potential anti-competition agreements could not be fully covered. The listed elements may be deliberately avoided in the agreements by pharmaceutical manufacturers, thus causing the whole detection system to be ineffective. The author suggests including a predictive analysis to include those agreements do not have the listed appearance but may lead to increased drug prices or reduced consumer choice in the scope of the review, by which the author constructs a two-step antitrust review initiation system is as follow in table 2.

<table>
<thead>
<tr>
<th>Predictive Market Analysis</th>
<th>Suspicious Appearance Elements</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Assume the agreement is executed</td>
<td>No foreseeable consumer’s choice reduction or price increase</td>
<td>No limitation on generic entry</td>
</tr>
<tr>
<td></td>
<td>Generic entry delayed</td>
<td>No value transfer</td>
</tr>
<tr>
<td></td>
<td>Consumer’s choice reduction or price increase foreseen</td>
<td>Value transfer</td>
</tr>
</tbody>
</table>

In situations where no increase in drug prices or reduction in consumer choice detected and without delaying the entry of generic drug manufacturers into the market, the possibility of reverse payment agreements existing is extremely low. As a result, directly allowing the parties to settle may meet balancing efficiency and risk requirements. In cases where the entry of generic drug manufacturers into the market is delayed, but no value transfer detected, if the parties can provide plausible reasons for the delay in entering the market, they may also satisfy the conditions for free of further review. Otherwise, it should still be transferred to the antitrust review agency for further examination. Including all agreements involving value transfer within the scope of the antitrust review follows the underlying logic that when the patent's validity is weak, the patented drug manufacturer fears that the patent may not meet the granting standards (such as those based on incomplete, misleading, or incorrect information). At this point, if a generic manufacturer files a lawsuit, the court is likely to rule the patent invalid. Therefore, the patented drug manufacturer, fearing the loss of the lawsuit, will tend to enter into a reverse payment agreement [15].

4.2 Establishing Agreement Filing System

In the pharmaceutical market, consumers are usually passive recipients in their interest struggle with original and generic drug manufacturers. Thus, the law must grant more initiative to private parties to fully protect consumer rights. Specifically, the US private enforcement system offers valuable insights. There should be an expansion of the scope of antitrust private enforcement. With the organizational strength of consumer associations, more consumers should be included in class-action lawsuits, providing more individuals with opportunities to assert their rights. Additionally, the agreement filing system adopted by the US and EU has achieved good results, saving the enforcement authorities the cost of discovering reverse payment agreements and reducing their likelihood. China can also adopt the agreement filing system, requiring original research drug manufacturers and generic drug manufacturers to file relevant agreements with the antitrust enforcement department, i.e., the Market Supervision Administration while reviewing the filed agreements and settlement agreements transferred by the courts in patent litigation. Deterrents can be created for manufacturers attempting to conceal reverse payment agreements by linking the related concealment behavior with financing, listing, and the credit system.

4.3 Utilizing the Antitrust Public Interest Litigation System in Reverse Payment Agreements Regulation

Consumer associations can play a significant role in antitrust regulation on reverse payment agreements. Consumer associations are instrumental in monitoring drug manufacturers’ anti-competition behavior. Through litigation, lobbying, and public awareness campaigns, consumer associations can on the one hand can supervise antitrust regulators to actively detect and strictly review agreements, on the other hand urge drug manufacturers not to violate competition laws, so that consumers' interests in affordable healthcare are protected.

The newly amended "Antitrust Law" of 2022, in its
second clause of Article 60, added an antitrust civil public interest litigation system, stating that "if an operator engages in monopolistic conduct that harms the social public interest, People's Procuratorates at or above the district level may file civil public interest lawsuits with the People's Courts according to the law." On August 1, 2022, the Supreme People's Procuratorate issued a notice, requiring the earnest implementation of the amended Antitrust Law, actively and prudently carrying out public interest litigation prosecution work in the field of antitrust, with a focus on areas such as the Internet, public utilities, and pharmaceuticals [16]. In regulating reverse payment agreements, antitrust civil public interest litigation has room to play a role and can be an essential direction for improvement.

Expanding the scope of prosecutorial public interest litigation to the antitrust field helps construct a civil, administrative, and criminal liability accountability system, fully leveraging the advantages and strengths of different departments, which both protects consumer rights and deters pharmaceutical manufacturers through a high amount of compensation [17]. Although Article 60 of the "Antitrust Law" restricts the subjects who can initiate anti-monopoly civil public interest litigation to the People's Procuratorates at or above the district level without specifying the consumer associations' status, this is a regrettable omission. However, according to Article 47 of the "Consumer Rights Protection Law," it is neither suitable nor should it be believed that consumer associations in provinces, autonomous regions, and municipalities cannot be engaged in anti-monopoly civil public interest litigation. Monopoly behaviors are often indistinct and secretive, and the party implementing the monopoly is clearly superior. Therefore, a solid organization to counter monopolistic enterprises is necessary. Consumer associations have been developing in China for over thirty years and have developed and effective a mechanism to protect consumer rights, promptly reporting and stopping monopolistic behavior. Additionally, consumer associations have the ability to organize the individual consumers into groups with shared interest, thus having the strength to counterbalance monopolistic enterprises [18].

5. Conclusion

Currently the precondition for reverse payment agreements to emerge in China's pharmaceutical market is already equipped. It is evident that enhancing regulatory measures for these agreements is imperative. This paper has offered a comprehensive approach to effectively regulate these agreements. By proposing the two-step antitrust review initiation system for patent settlement agreements, advocating for an agreement filing system, and suggesting utilizing antitrust civil public interest litigation, this paper outlines a framework that seeks to balance regulatory efficiency and risk mitigation.

This framework takes inspiration from the experiences of established regulatory frameworks in the United States European Union and European Countries. By adapting these lessons to China's context, government could work towards a more equitable pharmaceutical market where consumer's interest in affordable healthcare is ensured. This framework aligns with the ultimate goal of antitrust regulation, and contributes to the refinement of regulatory strategies in governing reverse payment agreements in China.

References


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16. Supreme People's Procuratorate, "Notice on Actively and Steadily Carrying out the Prosecution Work of Public Interest Litigation in the Anti-Monopoly Field"
