Research on the Antitrust Regulation of Unfair High Prices in the Field of API

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Abstract: The low elasticity of commodity demand and distorted market structure of APIs are the root causes of frequent unfair high price behavior. It is an urgent problem to eliminate such illegal activities and activate effective competition. Antitrust regulation is intended to stimulate competition with the most modest remedies possible. Ordering the cessation of an offence can prevent the further expansion of the consequences of damage in a timely manner, but the rules are too vague and should be properly refined, namely, to identify feasible measures of cessation and increase the burden of non-compliance with the obligation of cessation. But the actual market behavior is very complex, the single relief measure is difficult to deal with properly. The divestiture remedy, in the short-term direct introduction of competitors. Make it a supplementary remedy to deal with "Persistent diseases". Proper law enforcement purposes must be implemented by proper law enforcement procedures. The active participation of operators in the debate is an important part of the evidence defense, in the different views of the balance of interests. At the same time, law enforcement agencies should guide operators to build an effective anti-monopoly compliance system to remedy the lack of ex post relief.

Keywords: Unfair high price, Divestiture remedy, Anti-monopoly compliance system

1. Introduction

APIs are the foundation for drugs to exert their efficacy, and changes in their quality and price will directly affect the quality and price of drugs. The quality and price of drugs are the most concerned issues for the general public, and they are also the key livelihood issues that antitrust concerns. When market entities take advantage of their dominant position, engage in illegal and monopolistic activities, seize high profits, restrict market competition, and harm the interests of unspecified consumers, law enforcement agencies should inevitably take a sharp sword out of their sheath. However, the inherent characteristics of APIs make the interpretation of illegal behavior more complex than in other fields. This not only requires an objective assessment of excessively high prices, but also requires judgment on the unfairness of excessively high prices. Furthermore, law enforcement agencies not only need to pay attention to the effectiveness of relief measures to ensure the innovative development of the API related market, but also to safeguard the public's health rights and fair rights, balancing the two and finding a suitable solution.

2. The impact of unfair and high price behavior in the field of API on market competition

The first paragraph of Article 22 of Chinese Anti-Monopoly Law stipulates that it is prohibited to abuse market dominance and sell goods at unfairly high prices. The unfair high price stipulated in this clause should have two meanings: firstly, the selling price of the product is abnormally high, and secondly, the excessively high price is obviously unfair. From an economic point of view, when marginal cost equals marginal revenue, the price charged by operators is abnormally high. Generally speaking, there is not much controversy about what constitutes abnormally high prices, which tends to be based on objective judgments. And what constitutes a blatantly unfair price is actually determining the substantive impact of behavior on competition to delineate the boundaries of illegality, which tends to be subjective value judgments. The American Antitrust Law puts forward the basic principles on the determination of illegal monopoly behavior, namely the principle of self-illegality and the principle of reasonableness.[1] With the deepening development of the market economy, many behaviors that were once considered illegal may also show a more beneficial side to market development. For the regulation of abusing market

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dominance, it is difficult to adopt the principle of inherent illegality at both the institutional design and implementation levels.[2] The unfair high price behavior is more unique. Its illegality determination involves many factors such as effective competition, freedom of economic activity, distributive justice and fair trade. To grasp the reasonable scope of these aspects in law enforcement, I am afraid that it will cost a lot of law enforcement resources. On the other hand, regarding what constitutes unfairness, relying solely on logical reasoning is not persuasive enough. Due to its inherent meaning, it will evolve continuously with changes in the external environment. Therefore, in order to properly summarize, it inevitably requires the accumulation of practical experience. Based on this, some countries represented by the United States, according to utilitarianism, proposed that the anti-monopoly regulation of unfair high price behavior may achieve the purpose of law enforcement, but the cost of law enforcement is too large, so the simple unfair high price behavior should be put on hold.

In the field of antitrust, this phenomenon is further exacerbated by the fact that legal rules are often abstract and market activities are highly flexible. Law enforcement agencies are increasingly finding it difficult to rely solely on limited substantive rules to handle cases, which is more manifested as a discretionary process of "discretionary decision-making".[3] For unfair and high priced behavior, law enforcement officials need to be based on the facts of the case, the law, and the spirit of the law, balance various advantages and disadvantages impartially, determine the boundaries of illegality, and make an appropriate and necessary discretion. This is really not a simple matter. The European Court of Justice's determination of unfair high prices selects the economic value of the goods themselves as the reference standard. That is to say, when the price of a certain commodity or service is not reasonably related to its economic value, and the price is higher than its economic value, it is an unfair high price.[4] What is the inherent economic value of a commodity? This is actually a new issue in law enforcement practice. Chinese scholars have attempted to propose based on the theory of effective competition that in order to protect the interests of consumers, especially to safeguard their fair trading rights, antitrust laws should theoretically require monopolistic enterprises to maintain the prices of their products or services at a level that is suitable for effective market competition.[5]

Pricing freedom is the core of a market economy, where operators can set the prices of goods independently. When the prices of goods are high, it means that the market is profitable and will stimulate new competitors to enter. Of course, even if the other party can enter, it can still initiate a second round of predatory pricing to drive them out, but as long as the entry barrier is not high, there will continue to be people attracted by monopoly profits.[6] However, independent pricing does not necessarily mean arbitrary pricing, and in practice, high prices of goods do not always attract new competitors. An excessively tilted price balance may evolve into competitive resistance. In a relevant market, the operator's ability to maintain high prices of goods for a long time indicates that the market mechanism has failed. In the state of market failure, high price makers will further strengthen their monopoly position, extract more monopoly profits and aggravate the disordered market structure. In other words, the longer the illegal monopoly lasts, the deeper the harm to the market and the heavier the degree of competition restriction, which will inhibit the innovative development momentum of the market, destroy the allocative efficiency of resources, and cause unfair distribution.

In the field of API, such behavior has its unique impact on market order. APIs, as essential ingredients for drug efficacy, have low or even no demand elasticity. Operators can transfer the upstream market dominance to the downstream formulation production market, achieving monopoly power in controlling both markets simultaneously. According to general market rules, operators will control the supply of goods in order to maintain unfair high prices. The shortage of APIs means a shortage of pharmaceutical preparations, which not only damages the downstream market order and the legitimate rights and interests of consumers, but also may harm the legitimate rights and interests of the wider public.

3. Analysis of the Current Situation of Anti-Monopoly Regulation on Unfair and High Price Behaviors in the Field of API

3.1. Current Situation of Anti-Monopoly Regulation on Unfair and High Price Behaviors

The standardization of law enforcement is increasingly improving. Chinese Anti-Monopoly Law has only been implemented for ten years. In addition to the immaturity of the system itself, there is also a significant gap in the legal status, experience, and ability of law enforcement agencies compared to countries with a long history of anti-monopoly law.[7] For example, in the first APIs monopoly case the Promethazine Hydrochloride APIs monopoly case, the National Development and Reform Commission did not clearly disclose the specific laws and regulations that the two pharmaceutical

companies violated in the punishment decision, which reduced the credibility of the punishment.[8] In 2017, in the penalty decision for the monopoly case of isoniazid raw material, key information related to the determination of unfair high prices, namely the sales volume and prices of the raw material, were not publicly disclosed. After institutional reform, antitrust law enforcement agencies promptly publish punishment decisions, and should disclose necessary information that can be made public as much as possible to promote rational law enforcement and improve the credibility of law enforcement. At the same time, law enforcement agencies have changed their passive mode and actively investigated possible illegal and monopolistic behaviors in this field.

The enthusiasm of API operators in participating in the law enforcement process has increased. For the abuse of market dominance behavior, law enforcement agencies generally adopt the "Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Monopoly Civil Dispute Cases" regarding the allocation of the burden of proof, that is, law enforcement agencies determine that the operator has a market support position in the relevant market and has engaged in abuse behavior, and the operator believes that the behavior is legitimate and should provide evidence to defend it. In the case of isoniazid APIs monopoly, the operator did not raise any objections to the discretionary actions of law enforcement agencies and waived their right to legitimate defense. This is not conducive to achieving the purpose of antitrust regulation. Law enforcement agencies are gradually realizing that encouraging operators to actively provide evidence for defense can compensate for the lack of law enforcement experience and coordinate the rationality of discretion.

Anti-monopoly law enforcement constantly strengthens the responsibility to improve deterrence, and at the same time, gropes to establish the operators' anti-monopoly legal culture. Law enforcement agencies are continuously increasing their efforts to investigate and punish such behaviors, and the proportion of fines is showing an upward trend. On the other hand, law enforcement agencies realized that simply imposing fines could not achieve the purpose of regulation, and began to cultivate operators' anti-trust legal culture and guide operators to actively abide by the law. For example, in the 2021 phenol APIs monopoly case, the parties involved organized management personnel at all levels of the company to learn legal and regulatory knowledge such as the Anti-Monopoly Law, enhance the legal and responsibility awareness of the enterprise, and further standardize its behavior. Law enforcement agencies used it as a basis for mitigating punishment, and ultimately only imposed a fine of 1% of annual sales on the parties involved. This law enforcement method of combining leniency and severity is more in line with the spirit of antitrust law. More importantly, it will also serve as an educational demonstration for other operators, encouraging them to active learning and comply with anti-monopoly laws.

3.2. Existing Issues in Anti-Monopoly Regulation of Unfair and High Price Behaviors

Firstly, a single behavioral remedy measure is difficult to deal with complex market behavior and achieve the purpose of antitrust regulation. The appropriateness of remedial measures for illegal acts that have caused harmful consequences will affect the subsequent actions of offenders and potential offenders. Potential violators will not engage in illegal activities when they know that their net income is negative, thus achieving effective deterrence; On the contrary, it may lead to insufficient deterrence and indirectly encourage them to carry out relevant actions.[9]Article 58 of the Anti-Monopoly Law stipulates that for concentration of business operators that may cause harmful consequences, relief measures such as disposing of shares or assets within a specified period shall be taken. Article 56 and Article 57 of the Anti-Monopoly Law stipulate that for illegal monopolistic acts that have caused harmful consequences, three types of remedial measures are ordered: cessation of illegal acts, fines, and confiscation of illegal gains. The remedial measure of ordering the cessation of illegal activities undoubtedly has the least impact on the market and can timely curb illegal activities. From practical experience, the effectiveness of these behavioral relief measures is minimal. For example, in 2021, Tianjin Tianyao Pharmaceutical Co., Ltd. was fined 44.0226 million yuan by the Tianjin market regulatory department for reaching and implementing a monopoly agreement on fixed price changes and market segmentation in the sales of acetic acid fluoroethylene API. On November 17, 2022, we once again received the "Administrative Penalty Notice" issued by the Tianjin Market Supervision and Administration Commission, stating that its controlling subsidiary, Jinyao Enterprise, abused its dominant market position and sold Camoxetine injection at an unfair high price, resulting in a planned fine of 27.72 million yuan. The relief measures in 2021 do not seem to have had a deterrent effect on the actions involved in the punishment in 2022; Even the relief measures in 2022 may have limited deterrent effects on Tianjin Tianyao Company. Indeed, behavioral relief measures can promptly prevent the expansion of damage. However, under the current relief measures, unfair and high priced behaviors in the field of API have not been completely eradicated.

Secondly, the discretionary power of law enforcement agencies is relatively large, and the supply of

systems to ensure the proper exercise of this right is insufficient. There are obvious flaws in the standardization of law enforcement. The high price behavior attribute is neutral, and as the active ingredient of a drug, the product attribute is relatively unique. This may lead to misjudgment of their actions by API operators, who firmly believe in the laws of a market economy. Therefore, the process of interpreting the basis of law enforcement is to popularize the spiritual connotation of antitrust law. If it is to convey the spirit of the law, the content of law enforcement documents needs to be clear, clear, and easy to understand. When law enforcement agencies identify unfair and high priced behavior, they should first clarify important factors such as the definition of the relevant market and the determination of market dominance. Of course, existing regulations and guidelines provide detailed reference factors for this. Over concretization of relevant concepts may lead to new problems. Do multiple specific factors need to be considered? Does it deviate from value judgment after considering multiple factors? In the publicly available punishment decisions, different law enforcement agencies have chosen different considerations in different cases, but have not provided a basis for choosing this factor. So, can violators recognize the root causes of their illegal behavior based on the punishment decision? Can reasonable expectations be formed for legal norms? Once the premise of the certainty of the consequences of the behavior no longer exists, then strengthening deterrence to achieve the goal of preventing and restricting competitive behavior will lose its foundation.[10]

Thirdly, the antitrust compliance system already established by API operators has not played a substantive role. The initial understanding of antitrust laws by market entities in Chinese may have been in 2008, but to this day, it has only been more than a decade, and their understanding of the legislative spirit may not be thorough. Some market entities may still have a habitual monopoly mindset, believing that they have the right to speak and a competitive advantage when they are young, often abusing their dominant market position, and ignoring the existence of antitrust laws.[11] In recent years, the law enforcement efforts in the field of API have been continuously strengthened, but the results have not been ideal, indicating the lack of external prevention and control. In the face of a modern market economy, there is an urgent need for mechanisms that can stimulate the vitality of internal prevention and control. In fact, law enforcement practice has also proven that an effective antitrust compliance system is a powerful tool for preventing and detecting monopolistic behavior. The excellent performance of antitrust law implementation can be attributed to the proactive compliance of enterprises and individuals. The poor effectiveness of antitrust regulations in the field of API and even the frequent occurrence of "recidivism" also proves that the established antitrust compliance system is not perfect, or that the construction of this system is only a means for operators to exchange law enforcement trust.

4. Improvement Measures for Anti-Monopoly Regulation of Unfair and High Price Behaviors in the Field of API

4.1. Relevant regulations on improving remedies for unfair and high priced behaviors

This article suggests adding possible measures for violators to stop restricting competition after the clause on "ordering cessation of illegal monopolistic behavior". If the obligation to pay fines is not fulfilled, the responsibility for imposing additional fines will be borne, and if the obligation to stop illegal activities is not fulfilled, the possible liability should also be increased. If unfair and high priced behavior has the effect of restricting competition, disrupting competition order, and reducing consumer welfare, relying solely on legal sanctions cannot be effectively implemented, and appropriate remedial measures are needed to remedy it.[12] In the process of antitrust enforcement, it is also necessary to consider costs and benefits. Market behavior is becoming increasingly complex and secretive, and a single behavioral relief measure appears ineffective. The longer the unfair and high priced behavior occurs repeatedly or cannot be completely eliminated, the greater the harm to the competitive order, and the longer the subsequent recovery cycle will be. The distorted and solidified market trading structure is the root cause of unfair and high priced behavior in the field of API, and it is necessary to see the rabbit and the eagle in order to eliminate the hidden dangers. Stripping relief measures are a good strategy that can cultivate appropriate competitors in a relatively short period of time and activate markets that lack competition. In short, cutting off the structural basis for illegal behavior. When designing divestiture remedies, especially when adjusting the relevant market structure, special caution is needed to ensure not only the effective divestiture of concentrated assets that cause competitive damage, but also the formation of strong competition among operators who accept assets.[13] By using divestiture relief as a supplementary tool, we can eliminate "recidivists" who have repeatedly been banned. Although this measure is stricter, it cannot be ignored.

Behavioral relief measures and divestiture relief measures each have their own advantages and disadvantages. The power of antitrust enforcement agencies must be limited by the principle of proportionality, and the responsibility imposed on enterprises to end infringement must not exceed the appropriate and necessary scope to achieve the desired goals. Behavioral relief measures are like conservative treatment, with internal repair as the main approach and external adjustment as a supplement. Proper application is more beneficial for the development of relevant markets. The relief measures for divestiture can be described as bone scraping and detoxification, and should be carefully applied to prevent irreversible damage to relevant enterprises.

4.2. Improving the Standardization of the Anti-Monopoly Law Enforcement Process

To achieve law enforcement norms, it is usually necessary to define the relevant market, analyze entry barriers, and examine the effects of damage, in order to demonstrate legal facts.[14] Specifically, when it comes to unfair and high priced behavior, it is necessary to det ermine both the abnormally high prices and the illegal boundaries of high priced behavior. In law enforcement practice, identifying the illegality of unfair and high priced behavior is a major challenge. The so-called fairness is an abstract concept, and its meaning may be determined by a very small range of specific conditions. This cannot be solely derived from personal logic, but must be summarized through the accumulation of practical experience. From the perspective of consumers, due to the limitations of information density and way of thinking, their unfair and high priced illegal standards are relatively low. From the perspective of the operator, various factors that affect cost-effectiveness, such as environmental standards and production failure rates, will be comprehensively considered. At the same time, based on profit objectives, the perception of unfair high prices may be high. To achieve a balance between different interests and provide an appropriate outcome that is acceptable to all parties, law enforcement agencies need to follow the principle of proportionality and clarify the basis of law enforcement. More importantly, law enforcement norms ensure that the facts of the case and the basis for law enforcement are clear, which can provide guarantees for subsequent judicial supervision and also enable social supervision to play a certain role.

The truth becomes clearer as it is argued. In this information age, we are increasingly concerned about the impact of information on behavior patterns and outcomes. In every aspect of antitrust law enforcement, it is actually closely related to information processing. Operators inevitably have more effective information about the substantive effects of their own business activities. In many cases, if operators do not actively provide evidence, it is difficult for law enforcement agencies to obtain this information. Of course, this requires operators to attach importance to their own protection, preserve effective information, and form a standardized evidence chain. Overall, in the process of handling a case, it is possible for the operator to provide evidence and defense, and to weigh and choose interests in various information collisions, in order to find an appropriate conclusion. If law enforcement is aimed at restoring competition order, and further, the purpose of restoring competition order is for a better future, then in terms of a better future, the purpose of law enforcement entities and market entities should be unified. The active protection of legitimate rights by market entities is an important step towards rationalizing and standardizing antitrust law enforcement.

4.3. Improve the antitrust compliance system for API operators

Anti-Monopoly regulation of illegal activities is actually a process that focuses on both short-term effects (aftermath) and long-term effects (prevention). Both short-term and long-term effects aim to build a better future. So, guiding API operators to establish effective antitrust compliance systems precisely caters to this point. If compared to medical behavior, the antitrust compliance system is actually like "treating diseases", achieving the effect of "preventing the recurrence of diseases" by changing lifestyle and lifestyle patterns.[15] The establishment of an antitrust compliance system by operators is actually a change in the internal management system of enterprises, and an effective compliance system can urge enterprises to comply with antitrust laws. It is the common desire of antitrust law enforcement agencies in various countries (regions) for enterprises to actively comply with antitrust laws and regulations.[16] Of course, to establish an effective antitrust compliance system, it is necessary to guide law enforcement agencies and equip them with corresponding reward and punishment measures to ensure that operators can effectively implement the system in the long term. On the one hand, the punishment system has a deterrent effect, forcing operators to actively implement antitrust compliance systems. Law enforcement agencies should promote the commitment of operators to establish an antitrust compliance system. If they fail to fulfill their commitments, they will face adverse consequences such as antitrust regulations, loss of trading opportunities, and damage to goodwill. If serious violations occur, there is a possibility of

criminal risk. Operators may actively establish an antitrust compliance system to avoid being disadvantaged. On the other hand, the reward system is the driving force for operators to comply with antitrust compliance regulations for a long time. For example, the Korean Fair Trade Commission (KFTC) has established an antitrust compliance rating system, which provides differentiated incentives to enterprises based on different rating results. According to Article L464-2 of the French Commercial Code, if an illegal enterprise does not file an objection statement with the French Competition Authority and promises to establish antitrust compliance or upgrade and improve the existing antitrust system, it will receive an additional post event incentive of up to 10% penalty reduction.[17]

Operators themselves should recognize that compliance systems have a two-way effect, which can protect their legitimate rights from infringement and prevent infringement on others. Many operators have not paid attention to the aspect of compliance management in long-term practice. Even if they hastily establish compliance systems, they may only have beautiful skeletons and no standardized flesh and blood. Operators often fall into the misconception that 'compliance is equivalent to operating in accordance with the law and regulations'.[18] This often leads to vague compliance systems established by operators, and internal employees do not know how to implement them, making it difficult to play a practical role. For example, operators may be aware of the protection of trade secrets. For the construction of a compliance system for trade secrets, it may still be an unfamiliar concept. This may involve information management and preservation, personnel management, and emergency response strategies. In terms of this alone, it is already a comprehensive reform within the enterprise. API operators need to hire professional personnel based on their own situation to conduct risk assessments on the behaviors involved in their main areas of development and operation, and then develop a targeted compliance system. Of course, a targeted compliance system needs to be endowed with both authoritative and independent guarantee mechanisms within the enterprise to play its role. Firstly, the deterrence generated by heavy responsibilities drives all departments within the enterprise to strictly implement it, which is the key to the effective implementation of this compliance system. Of course, this premise is that the obligations set for employees in the compliance system should be as specific as possible. Avoid overly vague statements that make it difficult for employees to implement. Secondly, within the enterprise, a department should be established to supervise the operation of the antitrust compliance system, and supervise the daily behavior of each department to comply with the compliance system. The supervisory department needs to develop reward and punishment measures and promptly eliminate inappropriate systems that may trigger illegal activities. Finally, enterprises need to equip specialized personnel to closely follow the spirit of antitrust laws and make timely adjustments to the compliance system.

5. Conclusion

In recent years, although unfair and high priced behaviors in the field of API have been repeatedly investigated and punished, there has been no cessation of such behavior. Therefore, through case analysis, this article finds that there are still the following shortcomings in antitrust regulations. Firstly, a single behavioral remedy measure is insufficient to cope with complex market behavior and fails to deter the recurrence of illegal behavior. Secondly, there is a lack of competitive analysis on illegal activities, resulting in insufficient standardization of law enforcement. The operator did not actively exercise the right of defense to participate in the debate, resulting in a decrease in the credibility of law enforcement actions. Finally, simply increasing punishment cannot achieve the purpose of antitrust regulation and lacks an effective antitrust compliance system. In response to the above shortcomings, the following improvement measures are proposed. Firstly, improve the provisions for ordering the cessation of illegal activities, clarify the measures that may stop illegal activities, and supplement the responsibility for not fulfilling the cessation obligation. At the same time, the provision of divestiture relief will be used as a supplementary tool to severely punish "recidivists" who refuse to correct their mistakes. Secondly, law enforcement agencies should not only provide a detailed explanation of the facts of the case, but also conduct a competitive analysis of the illegal behavior and explain the law enforcement rationale. To achieve the effectiveness of antitrust law enforcement, it is necessary for operators to participate substantively in the enforcement process and find a fair and just balance between the interests of all parties in the debate. Thirdly, even the most perfect post event relief measures cannot perfectly repair the damage that has already occurred. To achieve pre prevention, law enforcement agencies should guide operators to establish effective antitrust compliance systems.

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