Evaluation and Analysis of Antitrust Enforcement in the API Industry in China

Yi-Jie ZHAO*, Lan-Fang FEIa

Law School, Ji’nan University, 601 Huangpu Avenue, Guangzhou City, Guangdong Province, China

*530333886@qq.com, afei27@hotmail.com

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Abstract. At present, monopolistic acts are frequent in the active pharmaceutical ingredient (API) industry, which exerts a serious impact on the normal functioning of the API market and pharmaceutical market. This industry is closely bound up with numerous patients and is a major livelihood issue. Antitrust enforcement agencies have investigated seven API antitrust cases. Based on these seven cases, this article will compare the similarities and differences between the National Development and Reform Commission and the Administration for Industry & Commerce (AIC) in law enforcement approaches and analyze the advantages and defects of antitrust enforcement in the API industry in China.

Introduction

Around 2010, the National Development and Reform Commission (hereinafter referred to as “NDRC”) began to notice API monopoly issue and set about investigating Reserpine Co API case. In 2011, the NDRC issued the first penalty on the company involved in API monopolized industries. At the moment, China was at the exploration stage of anti-monopolizing domestic drugs. [1] Afterwards, China’s antitrust enforcement agencies consecutively investigated seven antitrust cases in the API industry and fined them nearly 17.22 million yuan in total. In November 2017, the NDRC issued Guide for Pricing Behavior of Undersupplied Drugs and APIs Operators as an announcement[2], offering guidelines for various monopolistic pricing behaviors in the fields of undersupplied drugs and APIs.

Given that the pharmaceutical industry is a special industry that matters to national welfare and the people’s livelihood, how to regulate monopolistic conducts in the API industry and maintaining the competition order of the industry become one of important tasks of Chinese antitrust. At present, antitrust enforcement in the API industry has attracted close attention from both theory and practice circles. Besides the above reasons, more important reasons why it has such a great impact on social public are the reasonableness and legitimacy of antitrust enforcement and the reflections on relevant law issues in the enforcing process (Whether relevant market definitions are accurate? Whether the AIC and the NDR punished Qingyang at the same time is appropriate? What are its influences on market competition?)

Overviews of API-related Anti-trust Enforcement Cases in China and Analysis of Enforcement Approaches

Case Description

Since 2012, China has investigated and punished seven antitrust cases in the API industry. The notices of the penalty decision issued by antitrust enforcement agencies had conducted a specific analysis of the cases. The following are the brief descriptions of the cases of the notices.

Analysis of the Enforcement Approaches of the NDRC and the AIC

The form above shows that four cases were handled by the NDRC and three were handled by the AIC. The following compares the similarities and differences between the NDRC and the AIC in enforcement approach to explore the advantages and defects of antitrust enforcement in the API industry in China.
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<th>Case</th>
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**The Similarities.** The relevant market of API-related cases is defined mainly by the substitutability of the demand with consideration to the substitutability of the supply. In terms of defining the relevant commodity market, the relevant commodity market of six of the abovementioned seven cases is APIs themselves. This is related to the action mechanism of APIs themselves and quality standards for related products. The production of preparations must use standard prescriptions to ensure the safety, effectiveness and legitimacy of preparations. Under the strict standards, for preparation producers, APIs have no substitutes that only by using these APIs can API-related preparation producers produce preparations.

The determinations on whether monopolistic conduct have just cause are all analyzed in details. Although antitrust enforcement in China has not clearly pointed out whether the analysis of antitrust behaviors uses the illegal per se rule or the rule of reason. The seven API antitrust enforcement cases show that antitrust enforcement agencies adopt the rule of reason in the antitrust analysis of API. Taking estazolam API case handled by the NDRC as an example, in this case, there was no written agreement nor resolution between operators, but after investigation the NDRC determined that the three companies had communicated with each other through conference, meet, phone and short message and other means, reached a consensus on conspiracy to limit competition and acted accordingly [10]. The three companies all raised related grounds of opposition, but the NDRC carefully and thoroughly proved logical relations between legal requirements by conducting legal and economic analyses and determined that the behaviors of the three companies were consistent and their rising prices was a tacit consensus reached by contacting rivals rather than an operating decision made independently.
The Differences. The first difference in law enforcement is that the nature of the cases under their jurisdiction is different. Both the NDRC and the AIC are responsible for looking into monopoly agreement and abuse of market domination, corresponding to Chapter Two and Chapter Three of the Antitrust Law. But the difference is that the NDRC is responsible for price-related cases while the AIC is responsible for non-price-related ones. Among these seven antitrust enforcement cases, four cases handled by the NDRC involve either unfairly high selling price or fixed price; while three cases handled by the AIC involve refusal to deal or abuse of market domination with unreasonable conditions. This is corresponding to the positioning of law enforcement agencies.

The second difference is that they vary in the style of law enforcement. The NDRC is comparatively aggressive that most cases are enforced within three to six months, several are in three months, and its proportion of fines is higher than that of the AIC; the AIC is relatively prudent that most cases take a longer time, several are closed in six months, and the proportion of fine is normally lower, most is 1% to 3%. Their styles are also reflected by their written decisions that the written decisions of NDRC are terse and concise while that of the AIC are elaborate.

Merits of the Enforcement: the Reasonableness of Punishing Chongqing Qingyang by the NDRC and the AIC at the Same Time. In 2015, in the allopurinol API case, the AIC fined Chongqing Qingyang about 440,000 yuan, while the NDRC fined Chongqing Qingyang around 1.69 million yuan in the allopurinol tablets case. Both the two cases refer to allopurinol API market and Chongqing Qingyang, whether it is repeated punishment? After learning the details of the cases, it is found that the two cases are entirely different in nature, as they are two punishments against two illegal acts of Qingyang, so the NDRC and the AIC punished Qingyang at the same time is reasonable.

The reasonableness consists in the fact that the penalty decisions made by the two antitrust enforcement agencies both have a legal basis. At first, the two cases broke the law at different times. The unlawful act that the AIC investigated and treated was abuse of market domination and refusal to deal of Qingyang from October 2013 to March 2014; while the unlawful act that NDRC looked into is that Chongqing Qingyang reached and executed a monopoly agreement with the rest four companies involved from April 2014 to September 2015 when selling allopurinol tablets. Secondly, the related market of the two cases is different. The relevant market that the AIC defined was allopurinol API market, while the relevant market defined by the NDRC was allopurinol tablets market. Thirdly, the two illegal acts are different in nature that the AIC investigated abuse of market domination, corresponding to Article 17 of the Antitrust Law while the NDRC investigated monopoly agreement, which corresponds to Article 13 of the Antitrust Law.

To sum up, Chongqing Qingyang was not repetitively punished by two antitrust law enforcement agencies because of one conduct but was punished by the two agencies respectively because of its two unlawful acts.

Drawbacks: Weak Punishment Has Little Deterrent Effect on Competition Market. Chinese antitrust enforcement agencies have punished seven illegal API monopolistic conducts successively when they found them, which reflects the high attention paid to API monopolistic conducts from the agencies. However, API monopolistic conducts still occur frequently since the severity of legal punishment is weak.

Penalty proportion and amount are low. Taking allopurinol tablets case as an example, upstream and downstream medicine enterprises reached a monopoly agreement, and five companies thus acquired 80% to over 138% unlawful monopoly profit, while the NDRC only fined 8% and 5% of sales. There is a chasm between illegal monopoly profit acquired through monopoly agreement and fine proportion imposed by law enforcement agencies that the latter is negligible, so the fine imposed by antitrust enforcement agencies has no deterrent effect on illegal monopolistic behaviors, but may contribute to the continued spread of the same kind of unlawful acts because the cost of breaking the law is too low. [11] In the seven API antitrust enforcement, both proportion and amount of penalty are low. Among the cases handled by the NDRC, the highest proportion is 8%, the lowest is 2%; in the cases handled by the AIC, the proportion is 3%, 3% and 1% respectively. The low cost of breaking the law has little deterrent effect on competition market and affected the results of antitrust enforcement.
Conclusions

This article compares the similarities and differences between the NDRC and the AIC in law enforcement by analyzing seven antitrust cases in the API industry, sees the NDRC and the AIC accurately defined relevant market, they conducted concrete analysis of whether monopolistic conducts had just cause, rational division of labor among law enforcement agencies and their law enforcement style, and further analyzes the merits and demerits of their law enforcement. Chinese API antitrust enforcement agencies especially need to improve the drawback that penalty proportion and amount are low.

Lastly, there is a quotation from Zhang Handong, director of Bureau of Price Supervision of National Development and Reform Commission [12], “in the society with rule of law, law-enforcing departments shall enforce law by law and shall not be irrational for effects and impose illegal penalty. Law enforcement agencies will keep a tough stance and investigate and punish unlawful monopolistic acts when found with zero tolerance. With unremitting efforts, it is believed that there will be a radical change.”

Acknowledgement


References


