

A Closer Look At China's Landmark Pharma Antitrust Ruling

By **Vanessa Zhang, John Gong and Rita Li** (August 25, 2023)

In China, the pharmaceutical industry is oftentimes one of the key areas of antitrust scrutiny.

In 2021, China released the Anti-Monopoly Guidelines for the active pharmaceutical ingredient sector in consideration of the API sector's unique characteristics.

In general, the API marketplace is highly concentrated with high entry barriers, including complex technology, complicated production processes, patent protection and restriction of administrative approval.

In the past, antitrust enforcement by competition authorities has played an important role in regulating the API industry, although no relevant antitrust litigation had taken place in the judicial arena.

Yangtze River Pharmaceutical Group v. HIPI Pharma Tech, the first antitrust litigation in the API sector in China, saw its final verdict at China's Supreme People's Court on May 25.

This case is a landmark judicial decision as it is the first API-related case judged by the court, entirely overturns the lower court's verdict and involves a substantial amount of economic analysis. As such, this case provides constructive guidance for future antitrust litigation in the pharmaceutical industry.

Background

HIPI Pharma Tech, a Chinese supplier of raw materials for pharmaceutical products, developed a patented API-desloratadine citrate disodium compound and supplied it to Yangtze River Pharmaceutical Group, a Chinese pharmaceutical enterprise for the production of antihistamine Beixue tablets.

In 2019, Yangtze River Pharma filed an antitrust lawsuit at the Nanjing Intermediate People's Court alleging that HIPI had abused its dominance in the DCD API market through exclusive dealing, excessive pricing, tying and imposing unreasonable trading conditions.

The Nanjing court upheld Yangtze River Pharma's allegations and awarded the plaintiffs CNY 68.3 million (\$9.37 million) in damages. HIPI appealed and brought the matter to the court in July 2020.

On appeal, the court overturned the verdict of the first trial and determined that HIPI's alleged abusive conduct was in fact justified as legitimate business conduct and therefore did not violate the Anti-Monopoly Law.

As the economic witness on behalf of HIPI, we submitted expert reports and testified before the court. This article elaborates on the highlights of the verdict including analyses by the



Vanessa Zhang



John Gong



Rita Li

expert economists as well as the implications of the case.

Relevant Market and Market Dominance

DCD is a raw material for two finished anti-allergic antihistamines, including Beixue, the tablet medicine produced by Yangtze River Pharma's subsidiary, and Ruipukang, the capsule medicine produced by HIPI Pharma's own subsidiary.

The market presents a unique type of market structure, called the Coasian market, postulated in the defendant's expert report, in which the supplier side is monopoly and the demand side is monopsony.

The court upheld the relevant market as the DCD API market in China due to no alternative for the production of the downstream drugs. The court did not entirely adopt the Coase theorem, but did take the monopsony factor into consideration when assessing HIPI's market power.

The stronger the correlation between the demand of the intermediate goods and the demand of the finished goods, the greater the indirect competitive restraints from the market of finished goods. It was thus necessary to estimate indirect competitive restraints, especially when inputs do not have close substitutes and are used in only one finished good.

In this case, HIPI supplied DCD API to only one external customer, Yangtze River Pharma, for the production of Beixue, which competes with other second-generation antihistamines downstream.

Moreover, there is no substantial barrier or cost for Yangtze River Pharma to switch to production of other competing drugs as it holds official production approvals for multiple second-generation antihistamine drugs, most of which do not have patent protection and exclusive production equipment requirements.

Based on these analyses, the court concluded that indirect competitive restraints from the downstream market weaken HIPI's asserted market power.

Analysis of Abusive Conduct

In this case, there are three forms of alleged abusive conduct, including exclusive dealing, excessive pricing and tying other unreasonable trading conditions.

First, the DCD API in the exclusive contract was an innovative patented product protected by the '998 patent. The exclusive dealing contract is thereby derived from the legal exclusivity of the patent.

Moreover, the lock-in effect from exclusive dealing did not exceed the patent protection scope, because the exclusivity restriction would expire around September 2021, one year before the expiration of the patent in August 2022.

Therefore, the court held that the exclusive dealing in question was justified by patent protection, as opposed to the abusive conduct prohibited by the Anti-Monopoly Law.

Second, regarding whether HIPI's API sale price at CNY 48,000/kg constituted excessive pricing, the court of first instance only considered the production cost, which was rejected by the court.

Instead, the internal rate of return, or IRR, calculation was used, a common practice to reflect the relative return against investment, which considers not only the production cost, but also the R&D cost as well as the success probability of new drug discovery as risk adjustment.

The court affirmed the reasonableness of this method proposed by HIPI to measure the excessive pricing. The allocation of R&D cost based on the supply ratio of API in two downstream drugs, as well as a separate calculation of the IRR for API for external sales, were also supported by the court.

The IRR of the DCD API was 24.4%, well below the IRRs of Chinese innovative drug companies, which are generally higher than 20% and may even reach 40% to 50%.

In addition to the IRR calculation, the API in question was not overpriced as compared to the significant economic value it conveys to the finished drug. It was evidenced that the price of API at issue accounted for only 4% of the price of Beixue, much lower than the price of APIs in other pharmaceutical preparations, effectively nullifying the exploitative aspect of the excessive pricing argument.

Despite its significant absolute value, the API's price increase did not necessarily lead to excessive pricing, given that the API was an innovative patented product with an introductory price at the beginning of sales.

HIPI's price increase was a reasonable price adjustment on the basis of the promotional low price over time, a phenomenon widely observed in many industries when a new product is introduced to the market.

The court agreed with this argument and also noted that the sales price of the API in question was only in the middle range of quoted prices from other second-generation antihistamine APIs, which further justified the reasonableness of the pricing.

In addition, the court assessed the competitive effects and consumer welfare. In 2017, HIPI raised the price of the API at issue to CNY 48,000/kg, but Yangtze River Pharma was still able to be grossly profitable and expanded its market share by moderately decreasing its price of Beixue. Therefore, consumers were not harmed.

Third, the court dismissed the plaintiffs' allegations of tying and imposing unreasonable trading conditions. The court concluded that the tying conduct claimed by the plaintiffs should be analyzed in the context of the alleged excessive pricing, which was not sustained in this case.

The court also noted that there was neither sufficient evidence of unreasonable trading conditions nor sufficient evidence that HIPI obtained an illegitimate interest, or that the plaintiffs' interests were harmed due to the alleged conduct.

In short, the court determined that HIPI did not engage in abusive conduct and completely overturned the first instance judgment by the lower court.

Implications

As the first Chinese antitrust case in the field of APIs, this case represents a significant milestone in the history of antitrust private litigation in China. Through its analysis, the

court provided practical guidance for similar cases in the pharmaceutical industry. The main takeaways from this case are:

Economic analytical tools provide support for the Chinese judiciary in the pharmaceutical sector.

This case shows that economic analysis conducted by expert witnesses has been increasingly adopted by the courts in China and provides solid evidence for assessment of alleged abusive conduct.

For example, in this case, the IRR of the innovative API that factors in multiple crucial parameters such as R&D costs and the probability of R&D success is a good measurement tool for assessing excessive pricing.

Another example is that, although the Coase theorem introduced in the market definition was not directly adopted by the court, the market structures implied from this theory also enlightened the court's ongoing discourse on market power by considering the buyer market power.

Justification of exclusivity for patented drugs reflects the Chinese judiciary's perspective on innovation.

In contrast to previous enforcement penalty decisions against abusive conduct by Chinese regulators in the pharmaceutical sector, the court has stoked a better balance between competition concerns and intellectual property rights protection.

It has considered the unique patent attributes of the pharmaceutical industry, and has granted the protection of innovation by China's judicial authorities, affirming that the lawful exercise of intellectual property should be protected and not prohibited by antitrust laws.

This also evidences the court's cautious attitude in assessing exploitative abuse and excessive pricing. The court affirmed that the market itself can redress temporary overpricing and that market competition may only be harmed if the price squeeze is caused by excessive pricing imposed by the dominant entity.

In short, the court's decision in this case represents a milestone in China's judiciary. It balances intellectual property rights protection with antitrust regulation, while addressing the excessive pricing allegations. This decision also provides guidance for business practices in the innovative sectors in China, especially for those multinational enterprises holding patents and operating in China.

Vanessa Zhuang is a principal and practice leader of the Asian antitrust and competition practice at The Brattle Group Inc.

John Gong is an academic adviser at the firm.

Rita Li is a consultant and senior manager at the firm.

Fordham University professor James Keyte, Brattle Group senior consultant Michelle Cleary and principal Veronica Irastorza, contributed to this article.

Disclosure: Vanessa Zhang and John Gong were experts on behalf of HIPI and submitted expert reports and testimony in Yangtze River v. HIPI.

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