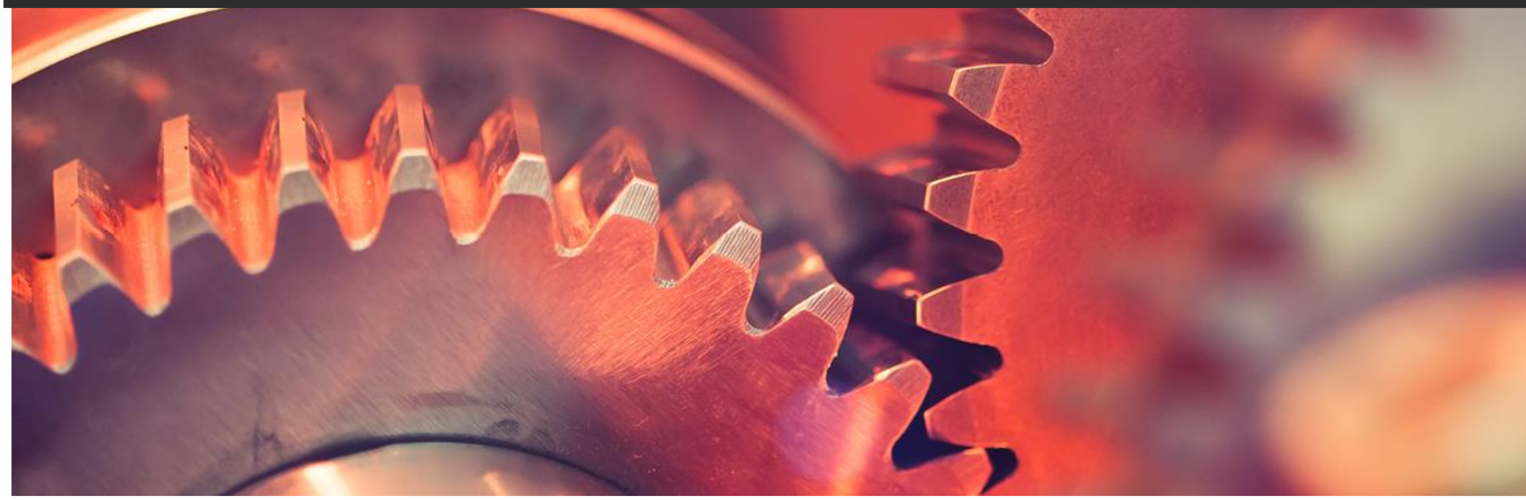
GT GreenbergTraurig

Alert | Antitrust Litigation & Competition Regulation



July 2023

In a Landmark Decision, China's Supreme Court Reverses Lower Court Decision Banning Excessively High Prices on a Patent-Protected Pharmaceutical Product

On May 25, 2023, following a three-year appellate review, the Supreme People's Court (SPC) rendered its final decision, reversing a lower court's finding, against HIPI Pharma Tech (together with its affiliates, HIPI) for abusive exercise of HIPI's market dominance. HIPI had charged its distributor, Yangtze River Pharmaceutical Group (together with its affiliates, Yangtze) an excessively high price for sales of the ingredient loratadine, manufactured by HIPI, and whose product was protected by a valid patent of HIPI. SPC also overturned the lower court's decision requiring HIPI to pay Yangtze civil damages totaling over RMB 70 million. Reversing the lower court's decisions in its entirety, SPC cautioned prudence when the court is reviewing abusive conduct such as excessive pricing, which was in general welcomed by the pharmaceutical industry as a pro-innovation move.

Background

HIPI manufactures both the ingredient loratadine, an antihistamine, and loratadine as a finished pharmaceutical product. Yangtze, a pharmaceutical manufacturer and distributor, purchased the ingredient loratadine from HIPI since 2008 for manufacturing the finished product loratadine. HIPI owned the patent of the loratadine compound, and since 2008, had collaborated with Yangtze to manufacture the ingredient loratadine and to manufacture and sell the finished product. In 2017, Yangtze and HIPI entered a long-term sales contract under which Yangtze agreed to purchase at least 5,000 kilos of the ingredient loratadine from 2017 through 2022 at a fixed unit price of RMB 48,000 per kilo (which was raised from a unit price of RMB 15,779 per kilo). Yangtze agreed to pay certain liquidated damages to HIPI if Yangtze purchased the ingredient from another supplier. In 2019, Yangtze litigated to invalidate the long-term sales contract on the grounds that the exclusive supply clause, the high unit price, and certain other associated arrangements constituted an abuse of HIPI's dominant power in the market for ingredient loratadine and sought civil damages. The lower court upheld Yangtze's claims and required HIPI to pay damages to Yangtze. HIPI appealed the case to SPC seeking to reverse the lower court's decision.

Highlights of SPC's Ruling

In its 175-page judgment, SPC scrutinized the validity and the extent of coverage of HIPI's compound patent, analyzed Yangtze's claims and HIPI's counterclaims, and answered a series of important issues under the Anti-Monopoly Law (AML) including the relationship between exploitation of IP rights and abuse of market power, before deciding to reverse the lower court's findings.

a. *Definition of relevant market*

In identifying the relevant market, SPC started with Yangtze's proposition that the ingredient loratadine constituted a single product market and then analyzed substitutability on both the demand and supply side. On the demand side, SPC emphasized that the ingredient loratadine is irreplaceable to customers (like Yangtze) manufacturing the finished product loratadine, and such ingredient-product correlation needs be reported to and reviewed by National Medical Products Administration (NMPA) when they approve the finished product manufactured by the customers. On the supply side, SPC noted both that each pharmaceutical ingredient must be separately authorized by the NMPA and can be manufactured only by a licensed manufacturer with valid GMP certifications, and that the compound of ingredient loratadine is protected under a valid patent during the litigated period, and thus other suppliers cannot readily switch to manufacture the ingredient loratadine. In conclusion, SPC held that the ingredient loratadine is irreplaceable in terms of both demand and supply, thereby forming a distinct product market. SPC held that the geographic market for the ingredient is China.

Following this conclusion, SPC referred to the "intermediate product" nature of the ingredient loratadine and noted that since the demand of an intermediate product emanates from the demand of the finished product, the court can consider the competition effect in the downstream market when identifying the relevant product market. SPC further opined as a rule that, if the competition in the downstream market passes through to the upstream market and has "significant" constraining effect on the suppliers in the upstream market, the court should consider the downstream market when defining the product market. But in the current case, SPC noted that HIPI had presented no meaningful evidence supporting the "pass-through" effect of the downstream competition, and thus they would not consider the downstream market when identifying the product market.

b. *Dominance in the relevant market*

As for market power, SPC noted that HIPI was the sole supplier in the market for the ingredient loratadine and thus was presumed to have dominance in the relevant market. In the downstream market of second-generation antihistamines (including loratadine as the finished product), SPC noted, there are substantial similarities between different antihistamines in terms of their indications, efficacy, pharmacological mechanism, and channel of sales. SPC continued to examine the competition landscape in the downstream market and found that manufacturers of one antihistamine product can switch to manufacture another antihistamine product without substantial obstacles. Consequently, according to

SPC, HIPI's dominant status in the upstream ingredient market was weakened by the close competition in the downstream market of antihistamines.

c. *HIPI's abusive conduct*

The lower court had found that HIPI committed two primary types of illegal abusive conduct unfairly exploiting its dominant market power: (1) HIPI required Yangtze to exclusively purchase from HIPI at a minimum 5,000 kilos of ingredient loratadine during the five-year term of the sales contract, and (2) HIPI charged an excessively high price for the sales. SPC refuted each finding of the lower court, analyzing the pro- and anti-competition effect of each alleged conduct.

In terms of the alleged exclusive dealing, SPC first acknowledged that the alleged conduct had a noticeable foreclosure effect, as the minimum purchase amount (i.e., 5,000 kilos) constituted 75% of Yangtze's demand during the five-year term. However, as held by SPC, if the anti-competition foreclosure effect is a necessary result of the dominant company's proper exercise of its IP right without exceeding the permissible limit of the IP right as prescribed by law, such conduct shall not be held as an illegal conduct prohibited under AML. Based on the holding, SPC identified that HIPI held a valid compound patent during the litigated period and had not licensed any third party to implement the patent for manufacturing activities, and that the patent remained valid when the minimum purchase target was satisfied. Thus, the exclusive dealing arrangement was a necessary result of implementing HIPI's patent right and thus did not violate AML.

When examining the alleged excessive pricing, SPC first upheld a general rule that a dominant supplier shall not be deemed to have violated AML by charging an excessively high price on the grounds that the excessive pricing may later be corrected by the competition, and banning such excessive pricing outright will have a "chilling effect" on market players, stifle innovation, and eventually damage consumer welfare.

Following the general rule, SPC explored Yangtze and HIPI's economic analyses and found that HIPI's internal returns rate (as adjusted by factoring in the innovation risk) from ingredient sales was not excessive as compared to the average market rate, and the marked increase from the precedingly effective unit price of RMB 19,900 per kilo to RMB 48,000 per kilo. Though disproportionate to the corresponding increase of HIPI's manufacturing cost, it could be justified on the grounds that HIPI offered the previous unit price of RMB 19,900 per kilo at a discount to promote the product.

SPC then checked the competition effect on Yangtze and the impact on consumer welfare by HIPI charging the unit price of RMB 48,000 per kilo. SPC found that the revenue that Yangtze realized from sales of the finished product of loratadine increased, and the retail price of the finished product decreased slightly during the term of contract. SPC thus concluded that HIPI had caused no anti-competition effect or damage to the consumer welfare by charging the said unit price.

Authors

This GT Alert was prepared by:

- Yuqing (Philip) Ruan | +86 (0) 21.6391.6633 | ruanp@gtlaw.com
- Dawn (Dan) Zhang | +86 (0) 21.6391.6633 | zhangd@gtlaw.com

Albany. Amsterdam. Atlanta. Austin. Berlin.¬ Boston. Charlotte. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Houston. Las Vegas. London.* Long Island. Los Angeles. Mexico City.+ Miami. Milan.» Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Portland. Sacramento. Salt Lake City. San Diego. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Singapore.⁼ Tallahassee. Tampa. Tel Aviv.^ Tokyo.¤ Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.