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## Supreme People's Court offers much-needed guidance following high-profile monopoly dispute involving pharma patents

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In one of China's "Ten Exemplary Anti-monopoly and Unfair Competition Cases of 2023" (a list that was released on 14 September 2023), the Supreme People's Court has elucidated the correlation between the market foreclosure effect and the exercise of patent rights. The impact of this decision is still being felt as it helps to establish stable jurisprudence in terms of active pharmaceutical ingredient (API) monopoly assessment involving patents.

#### Case background

In 2002, HIPI Pharma Tech developed the blockbuster anti-allergic drug desloratadine citrate disodium and applied for a patent, which was granted under the number ZL02128998.0 (patent '998). Afterwards, HIPI transferred the patent to its subsidiary Hefei Enrute Pharmaceutical, which manufactured and sold the API in the form of capsules.

In 2006 Yangtze River entered into a technology licence agreement with HIPI. Under the agreement, Yangtze River was exclusively licensed to sell the patented product in tablet form and HIPI was barred from entering the tablet market. However, the exclusive licence did not extend to the production of the API, so Yangtze River had to procure the API from Enrute. Yangtze River instructed its subsidiary, Hairui, to manufacture and sell the tablets using the API supplied by Enrute.

Throughout the decade-long partnership, HIPI hiked the API's price several times, citing a surge in costs.

In May 2019, Yangtze River initiated civil litigation against HIPI before the Nanjing Intermediate Court. It claimed that HIPI had abused its dominant position in the API market and had unreasonably raised the API price – so much so that it squeezed on the profit margin for the tablets, thus giving HIPI's capsules an unfair competitive edge in the market. Yangtze River requested cessation of monopoly conduct and damages of 90 million yuan.

On 18 March 2020 the Nanjing Intermediate Court ruled in favour of Yangtze River and awarded damages of over 68 million yuan. One month later, HIPI appealed before the Supreme People's Court IP Court (SPC IP Court).

Before the SPC IP Court, HIPI contended that:

- the API, a compound with two crystalline water molecules, fell within the protection scope of patent '998, and the patent's contribution should be considered in the API's price;
- the therapeutic effects of Yangtze River's tablets were to be attributed to the API, which is, in essence, an innovative drug; and
- the sale of the tablets resulted in huge commercial success for Yangtze River.

#### The 2023 ruling

On 25 May 2023, the SPC IP Court ruled in favour of HIPI. The court issued a landmark decision that still serves as a point of reference for monopoly assessment of patented APIs and construction of the protection scope of compound patents.

The court overturned the first-instance judgment based on the following.

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The API fell within the protection scope of patent '998.

- HIPI's exercise of its valid patent did not constitute exclusion or restriction of competition under the Anti-Monopoly Law.
- It is highly likely that HIPI initially offered the API to Yangtze River at a promotional price and the subsequent price increase was a reasonable adjustment – Yangtze River's argument that the API price hike was higher than the surge in the cost of raw materials used to manufacture it was untenable.

The decision has now entered into force.

Welcome guidance on patents and monopolies

This ruling provides valuable guidance when it comes to the assessment of monopolies.

The relevant market, as defined by the Anti-Monopoly Law, refers to the product or territorial scope that business operators compete in during a certain period of time for specific commodities. The court observed that the relevant market can be assessed on a case-by-case basis by analysing:

- the demand-side substitution over the specific commodities directly involved in the litigious monopoly conduct; or
- the supply-side substitution, where competitive constraint over the business operator is analogous to demand-side substitution.

In the pharma sector, APIs and their preparations form a strict corresponding and deep association; APIs are irreplaceable for the manufacture of its preparations from both a demand-side and supply-side substitution perspective. Therefore, the court ascertained that the relevant market in this particular case is the API market.

The Anti-Monopoly Law states that an undertaking of an entity whose market share amounts to half of the relevant market may be presumed to have a dominant market position. However, this may not be determined as such a position if the entity has evidence to prove otherwise. Further, this dominant position could be partly undermined by either the direct or indirect practical competition constraint.

In this case, competition of the downstream preparation market could be passed along to the upstream API market and create competition restraint over API operators. The presence and extent of such restraint is vital to accurately assess the business operator's market presence and whether it has abused its dominant market position. HIPI's dominant position in the API market was weakened due to strong indirect competition constraints from the downstream market of the preparations of anti-allergic drugs. The competition from other anti-allergic drugs will inevitably affect API demand, which will then seep into the API market and create competition constraint over API suppliers.

In assessing the abuse of a dominant market position, the court took the following parameters into account:

- whether the business operator exercised any restriction over transactions;
- whether it set unfairly high prices for the specific commodity; and
- whether it attached any unfair strings to the transaction.

The SPC IP Court and Nanjing Intermediate Court both affirmed that HIPI had a dominant position in the API market. However, as HIPI did not abuse its market dominance, a monopoly could not be established.

The market foreclosure effect is an inevitable result of the execution of the technology licence agreement and HIPI's legitimate assertion of patent '998. If Yangtze River had procured the API from other unlicensed suppliers, it would have infringed on HIPI's patent. Based on the above findings, the SPC IP Court concluded that the price hike was reasonable and the exercise of the patent rights were justified and not monopolistic.

Looking forward

This elucidation of the correlation between the market foreclosure effect and the exercise of patent rights is a very welcome development in China. The decision will help to establish stable jurisprudence in terms of API monopoly assessment involving patents.