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n° 53 WHD Case: PT | Supreme People's Court offers much-needed guidance following high-profile monopoly dispute involving pharma patents

Yue Guan, 24 January 2024, first published by *IAM*

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 Enruite 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 Enruite. Yangtze River instructed its subsidiary, Hairui, to manufacture and sell the tablets using the API supplied by Enruite.

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.

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.

n° 56 WHD Insights: IP | IP Practice in China

Shuhua Zhang & Paul Ranjard, first published by *Chambers & Partners*

2023 has seen the confirmation of changes to the Chinese strategy relating to the administration and protection of intellectual property rights, which have had a significant impact on the level of administrative litigation.

Changes of strategy

In 2008 China announced the National IP Strategy for the Protection of Intellectual Property Rights, encouraging through all sorts of subsidies, awards and tax advantages, the filing of IP rights for invention patents, utility models, trademarks. The result was spectacular growth in the number of filings, mainly of utility models and trademarks. However, the quality of many of the applications, in particular of utility models and trademarks, turned out to be more and more suspicious.

For utility models, which are in principle granted after a simple examination as a formality, the then State Intellectual Property Office in charge of the registration of the rights, has had to modify the examination rules and start refusing "abnormal patent filings. In November 2021, the China National Intellectual Property Administration (which now oversees both patents and trademarks) launched the "Blue Sky" campaign against abnormal patent application and in 2023 there was only a slight increase of new patent applications in China in comparison with the previous years. In the first nine months, the number of granted utility models decreased by 25.5% in comparison with the same period of 2022.

In the case of trademarks, which have frequently tended to be filed by applicants who had no intention of using them but were merely interested in the potential resale value of the marks, the CNIPA has started to take measures against such "bad faith trademark applications". Subsidies have been cancelled, the work of patent and trademark agencies and agents have been scrutinised, and "trademark hoarding" have been targeted for sanctions. This new strategy has had an impact on the number of trademark filings. In 2022 the total number (7.51 million) was nearly two million lower than in 2021 (9.45 million), and in the first nine months of 2023, the total amount of trademark registrations granted decreased by 35.3% (1.71 million).

Such a decrease in the number of trademark applications resulted in a corresponding decrease in the number of opposition and invalidation cases, which was clearly felt by IP agencies.

Evolution of litigation practices, procedures and jurisdiction

As regards IP civil litigation, however, the situation remained stable. In 2022, People's courts rendered 457,805 judgements in domestic civil disputes, and 5,547 judgements in foreign related civil disputes (a percentage of 1.2%). However, with regard to foreigners, there is additional interesting data: in the past four years (2019-2022), 10% of the lawsuits submitted to the IP Tribunal of the Supreme Court (the court of appeal for technology related cases) were foreign related. One may safely conclude that

foreign related IP lawsuits cover a large portion of China's "high value IP cases". In 2023, from January to September, People's courts accepted 0.37 million new IP lawsuits, a slight increase of 1.61%. It is worth noting that the number of patent contract disputes raised by 42%; patent infringement and ownership disputes raised by 27%; technology related civil lawsuits increased by 56.7%. In other words, the rate of "high value" IP lawsuits has increased significantly in 2023.

In the case of IP enforcement, over the past few years Chinese courts have been faced with a trend called "commercial IP enforcement": hundreds of thousands of civil IP lawsuits with very limited value. IP owners collected some evidence of IP infringement against small sellers and filed civil lawsuits to collect damages instead of investing in the search of the source, ie, the suppliers or the manufacturers. The courts, overwhelmed with such cases, awarded deliberately low damages to discourage this kind of business model. On the other hand, the courts published exemplary judgements with high damages rendered against the manufacturers.

User-friendly Procedures

China joined the "Convention Abolishing the Requirement of Legalization for Foreign Public Documents" ("Apostille Convention") on March 8th, 2023. The Convention will become effective in China on November 7, 2023. China's embassies in many countries have already announced that they will no longer provide any legalisation services. This means that foreigners will be exempted from the lengthy legalisation procedure for many documents/evidence to be used in China's courts like the power of attorney to the Chinese lawyer (a notarisation will be sufficient).

After the COVID pandemic ended in 2023, the courts at various levels had to wind up pending lawsuits, which were delayed by the COVID restrictive measures, and had to deal with newly filed lawsuits. This was a big challenge. The Supreme Court found a solution by selecting intermediate courts to hear technology related lawsuits, allowing them to hire "technology investigators" to help in the fact finding and understanding of the technology, while nearly 600 basic district courts were to try simple IP disputes (such as trademark infringement).

Besides jurisdiction adjustments, the "intelligent Court" practice also contributed to the speeding up of the procedures. Even before the COVID pandemic, some courts had begun to move some procedures, like filing a lawsuit, online. During the three years of the COVID pandemic, more and more courts joined this practice. This practice was not limited to filing a lawsuit with the court. Pre-litigation settlement negotiation, cross-evidence examination, lawyer's brief, argument presentation and oral hearing all moved online. The practice remained after the COVID pandemic ended. Courts of different instances also use the electronic file transfer system to speed up the appeal process. All of these practices make litigation work more convenient and efficient for IP practitioners.

Conclusion

All in all, the IP field in 2023, like the economic situation, has witnessed a slowdown after years of consecutive increase. Competition has become ever fiercer, but there always remain opportunities. Only the fittest can survive and prosper.

n° 57 WHD Insights: PT | New guidelines for the patent term extension regime in China

Jicheng Yang, 19 January 2024, first published by *MIP*

The fourth amendment to China's Patent Law (Article 42) introduced a patent term extension (PTE) regime in China. The newly revised Implementing Regulations of the Patent Law and the Guidelines for Patent Examination, which will enter into force on January 20 2024, flesh out the much-needed details of the regime.

Article 42 of the Patent Law prescribes two types of PTE:

- An extension to compensate for an unreasonable delay in the prosecution process of an invention, which is the Chinese counterpart of the US patent term adjustment (PTA) mechanism (see part I); and
- An extension to compensate for the time required for obtaining administrative approval to market a new drug, which is the Chinese counterpart of the US PTE mechanism (see part II).

Part I: PTA 101 in China

Invention patents that have experienced an unreasonable delay in the prosecution process are eligible for a PTA, unless the applicant files on the same day an invention patent and a utility model for the same invention, and the invention patent is later granted (Article 9 of the Patent Law).

In principle, the request for a PTA shall be made by the patentee to the CNIPA within three months from the date of grant. In the transitional period between the entry into force of the fourth amendment of the Patent Law (June 1 2021) and that of the newly revised regulations (January 20 2024), an invention patent granted after June 1 2021 is eligible for a PTA (where examination commences after January 20 2024), provided that the PTA application is submitted within three months from the date of grant. Where a patent that is eligible for a PTA has expired before January 20 2024, a PTA can still be granted, with the extended term commencing on the original expiry date.

The extended term of a PTA shall be calculated as follows:

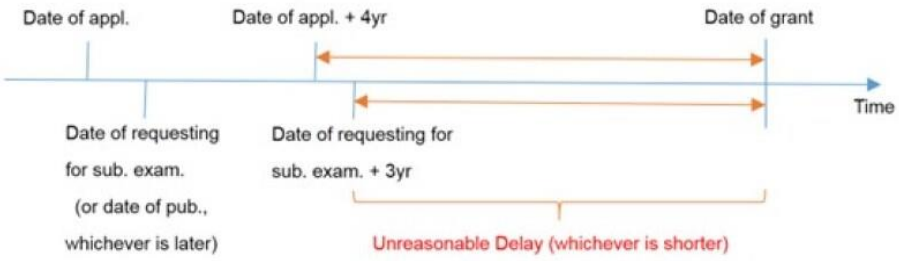
Extended term = unreasonable delay in the prosecution process – reasonable delay – unreasonable delay caused by the applicant

Unreasonable delay in the prosecution process

An unreasonable delay in the prosecution process refers to an undue delay in the date of grant. It is defined as the interval between "four years after the date of application", "three years after the date of requesting substantial examination", "three years after the date of publication", whichever is later, and the date of grant.

For Patent Cooperation Treaty (PCT) applications and divisional applications, the date of entry into the national phase and the date of filing divisional application shall be

deemed as the date of application respectively.



Reasonable delay

A reasonable delay shall be deducted from the extended term. The regulations set forth the below circumstances as qualifying as a reasonable delay:

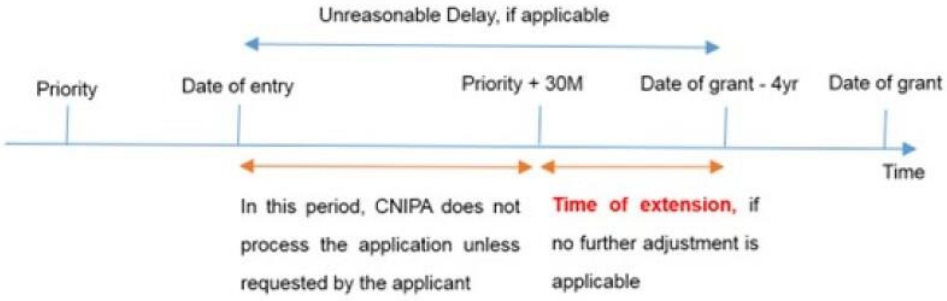
- Where the applicant has revised the application documents in filing a re-examination request or in response to the notification of re-examination in a re-examination proceeding;
- Where the examination has been suspended due to disputes over the right to file a patent application;
- Where the court has ruled to take preservation measures against the right to file a patent application; and
- Other eligible circumstances.

Unreasonable delay caused by the applicant

An unreasonable delay caused by the applicant (as shown below) shall also be deducted from the extended term:

- Where the applicant has failed to respond to an office action in due time;
- Where the applicant has requested for deferral of examination;
- Where the applicant has requested incorporation by reference;
- Where the applicant has requested restoration of right; or
- Where the applicant has not requested to process a PCT application prior to the expiry of 30 months from the priority date.

Article 23 of the PCT prescribes that a designated office shall not process or examine an international application prior to the expiry of 30 months from the priority date, in the absence of an explicit request by the applicant. Where the applicant does not make such a request, the interval between the date of entry into the national phase and the expiry of 30 months from the priority date shall be deducted from the extended term.



Examination and remedy

The examination of a PTA shall follow the principle of hearing; i.e., the applicant shall be given at least one opportunity to make observations and/or amend the documents.

The patentee and the third party that is involved in a patent infringement dispute may apply to the CNIPA for administrative reconsideration against a decision to grant/not to grant a PTA.

Part II: PTE 101 in China

Invention patents seeking protection over products, methods of preparation, or medical uses (Swiss-type) that are associated with approved innovative drugs or certain modified new drugs are eligible for a PTE.

In accordance with the drug registration classification system of China's National Medical Products Administration, patents associated with drugs in the following categories are eligible for a PTE.

For traditional Chinese medicine drugs or natural drugs:

- Innovative drugs; and
- Modified new drugs treating new indications.

For chemical drugs:

- Innovative drugs that have not yet been marketed in China or overseas;
- Modified new drugs that are the esterification or salification of known active ingredients; and
- Modified new drugs treating new indications.

For biologicals:

- Innovative vaccines and innovative biologicals for a therapeutic purpose;
- Modified vaccines utilising a new virus seed; and
- Modified biologicals treating new indications.

A novel drug that has been marketed overseas before filing an application for marketing approval in China will not be deemed as an innovative drug, and the

pertinent patents are therefore not eligible for a PTE in China.

On top of that, a patent that is eligible for a PTE shall meet the following conditions:

- The date of grant of the patent pre-dates the date of obtaining the marketing approval of the drug implementing the patent;
- The patent is valid;
- The patent term has not been extended by a PTE;
- A claim of the patent incorporates the technical solution of a drug that has obtained marketing approval;
- Where the drug implements multiple patents, only one patent may be granted a PTE; and
- Where a patent is implemented by multiple drugs, application for a PTE may be filed for only one of the drugs.

Application time limit

A request for a PTE shall be made by the patentee to the CNIPA within three months from the date of obtaining marketing approval. If the patentee is not simultaneously the holder of the marketing approval, written consent of the latter shall be obtained.

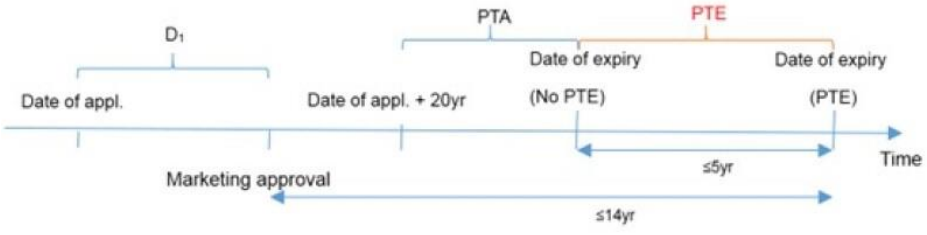
During the PTE of a patent, the protection scope of the patent shall be limited to the technical solutions of the approved new drug and the approved indications.

In the transitional period, a patent for which a PTE application is filed after June 1 2021 is eligible for a PTE, provided that the PTE application is filed within three months from the date of obtaining the marketing approval of the drug implementing the patent.

Calculation of the extended term

In practice, the patentee may request both a PTA and a PTE, should their invention experience an unreasonable delay in the prosecution process, and the patentee went through a lengthy procedure to obtain administrative approval to market new drugs implementing the invention. In such case, the length of the PTE shall be determined on the basis of the duration of the PTA, unless the patentee explicitly waives the PTA.

The term of a PTE, which is subject to the provisions of Article 42(3) of the Patent Law, is determined by deducting five years from the interval between the filing date of the patent and the date of obtaining marketing approval in China for the new drug. Specifically, the extended term is capped at five years, with the total validity period after obtaining the marketing approval capped at 14 years.



It can be observed from the above time axis that:

- PTE = the time between the date of application and the date of obtaining marketing approval (D1) – 5 years;
- PTE ≤ 5 years; and
- The interval between the date of obtaining marketing approval and the original date of expiry (20 – D1) + PTA + PTE ≤ 14 years

It can be deduced that:

- If D1 – PTA ≤ 6 years, a PTE cannot be obtained;
- If 6 years < D1 – PTA ≤ 11 years, the term of the PTE equals D1 – PTA – 6 years; and
- If D1 – PTA > 11 years, the term of the PTE equals 5 years.

Examination and remedy

The examination and remedy of a PTE is analogous to that of a PTA, except that a party that is eligible to apply for an administrative reconsideration could include a third party that has filed an application to obtain the marketing approval for a relevant drug.

Final comment on the PTA and PTE regime in China

It remains to be seen how the PTA and PTE regime will be implemented in China. Innovative and generic drug makers are advised to watch the CNIPA's case law closely to see if the agency will provide any further guidance on this matter.