China update – drug patents

First pre-trial injunction granted for a drug patent in China: *Astellas Pharma v Zhejiang Hisun Pharmaceutical*.

On 27 December 2019, the Beijing IP Court (the Court) granted the first pre-trial injunction in China, specifically for a drug patent. Although it is encouraging that the first pre-trial injunction has been granted in China, this may not be too exciting. This pre-trial injunction only provided six months protection to the patented product, notwithstanding that the patentee in this case had suffered from infringing sales for at least 14 months before the pre-trial injunction was granted, and it took the patentee nine months to have the pre-trial injunction request accepted by the Court for hearing. Having said this, the grant of pre-trial injunctions is not a common practice around the world. **Toby Mak** outlines the underlying law, which is an interesting reminder of the similar objectives to Western jurisdictions. The catch, he says, is in the evidence; the case itself shows some interesting parallels to arguments on 'clearing-the-way' cases in the UK, but also highlights the critical need for the right (independent) evidence in China.

On 27 December 2019, the Beijing IP Court (the Court) granted the first pre-trial injunction in China, specifically for a drug patent (ZL00801216.4) owned by the Japanese company Astellas Pharma Inc ('Astellas') against the defendant Zhejiang Hisun Pharmaceutical Co. Ltd. ('Hisun'). The drug at issue is for micafungin sodium for injection for treating fungus infection.

This is encouraging, as pre-trial injunctions are rarely granted in China. In fact, none has been granted in China according to the Chinese court decisions collected by Darts-IP, let alone granted for a drug patent. A regular criticism is that China does not protect IP rights effectively. While it is true that no pre-trial injunction has ever been granted in China until the present case, it is not easy to obtain pre-trial injunction in the West either as shown by the data below from Darts-IP:

Pre-trial injunctions granted from 1 January 2016 to 30 June 2020

US	UK	FR	DE	NL
5	3	4	15	3

The US, the UK, France and the Netherlands granted about one pre-trial injunction per year, while Germany granted about four per year. Before discussing the details of this case, I will first explain the legal basis of granting a pre-trial injunction in China, which is in some respects similar to the UK. (My observations are highlighted.)

Legal basis of granting pre-trial injunction

The Chinese Patent Law (2008)

Article 66 of the present Chinese Patent Law (2008), introduced in the previous 2000 version, reads as:

'Article 66:
If the patentee or interested party has evidence to prove that another person is committing or is about to commit a patent infringement, which unless being stopped in time, may cause irreparable damage to the patentee's lawful rights and interests, the patentee may, before taking legal action, apply to the People's Court order to order for the cessation of such act.

A bond must be provided when filing such an application. Otherwise, the application shall be rejected.

The People's Court shall make a ruling within 48 hours from the time of **its acceptance of the application** [emphasis added]. If an extension is needed under special circumstances, a 48-hour extension may be allowed. If a ruling is made to order to cease the relevant act, it shall be enforced immediately. The party that is dissatisfied with the ruling may file an appeal once, and the enforcement shall not be suspended during the appeal.

If the applicant did not take legal action within 15 days from the date the People's Court takes measures to cease the relevant act, the People's Court shall lift such measures.

If the application was found to be incorrect, the applicant shall compensate the losses suffered by respondent due to cessation of the relevant act.'

[The above provisions on pre-trial injunction remain unchanged in the latest draft of the next revision to the Chinese Patent Law. See my article on page 25.]

Stipulations of the Supreme People's Court on the examination of cases concerning act preservation in IP disputes

Pre-trial injunction in China is also governed by these stipulations effective since 1 January 2019, which set out the following:

Article 6 defines '**emergency**', specifically if one of the following is fulfilled:

1. The applicant (the IP right owner)'s trade secret is about to be disclosed.
2. The applicant's personal rights, such as publication right and privacy, is about to be infringed.
3. The intellectual property at issue is about to be disposed;
4. The applicant's intellectual property is being infringed or is about to be infringed at time-sensitive events, such as exhibitions.
5. Rights in a time sensitive 'hit show' are being infringed or are about to be infringed.
6. Other situations where it is necessary to take preservation actions immediately.

[According to article 1.6 of the US-CN trade agreement 2020, cases involving trade secrets should always be considered as emergencies.]

Article 7 defines the **factors** to be considered when examining a request for pre-trial actions including pre-trial injunction:

1. Whether the applicant's request has a factual basis and legal basis, including whether the validity of the requested intellectual property is stable.
2. Whether failure to adopt act preservation measures will cause damage, including that the applicant's legitimate rights and interests to be irreparably damaged, or make it difficult to enforce.
3. Whether the damage caused to the applicant by not providing preservation measures exceeds the damage caused to the respondent by imposing them.
4. Whether preservation measures harms the public interest;
5. Other factors that should be considered.

Special thanks to Darts-IP for providing the statistics of the grant of pre-trial injunction in CN, US, UK, FR, DE, and NL.

Article 10 defines '**irreparable damages**':

- The respondent's action will infringe the applicant's personal rights including irreparably damaging goodwill, publication rights or privacy;
- The respondent's action will make the infringement difficult to be controlled and substantially increase the applicant's damage;
- The respondent's action will significantly reduce the applicant's relevant market share;
- Other irreparable damages to the applicant.

[As in other areas of IP law in China, the above are not very different from the provisions on pre-trial injunction in the West. The catch lies in the difficulties in providing evidence acceptable to a court to fulfill the above requirements so that the IP right owner could actually obtain the pre-trial injunction. Fellow readers familiar with my articles should have a feeling how difficult it could be in China.]

Facts of the case

- Astellas obtained approval to sell micafungin sodium injection in Japan in 2002, and in China in 2006.
- Hisun applied for approval to sell micafungin sodium in 2013, and obtained the approval in 2018. [The Chinese Patent Law, specifically article 69(5), has the equivalence of the US Bolar exemption.]
- On 15 March 2019, Astellas filed a request for pre-trial injunction at the Court based on its patent, ZL00801216.4, ('**216**) directed to the drug micafungin sodium injection.
- The full term of '216 expired on 29 June 2020 – about 1½ years after the request for pre-trial injunction was filed.
- After the request for an injunction was filed, the Court held hearings on 26 March, 4 April, 10 May, and 25 July 2019, and finally on 26 December 2019. The decision was then handed down the next day on 27 December 2019. [While the requirement in the Chinese Patent Law that 'The People's Court shall make a ruling within 48 hours from the time of its acceptance of the application' was fulfilled in this case, this case took exactly nine months to be accepted by the Court. In fact, acceptance of the case by a court is the major catch. Many cases are simply not accepted by the Chinese courts, and therefore will not appear in any court statistics. In many cases, the reasons for non-acceptance are formalities related, for example, insufficient documents showing the person signing the power of attorney has the authority to sign (certificate of identity of the legal representative, the written resolution, memorandum of association, and the articles of association authorizing the legal representative). Lack

of sufficient proper substantive evidence is also another major reason, which could be arbitrary in some cases.]

- Hisun's 2018 annual report, published on 31 January 2019, revealed losses of between RMB 520 million and RMB 620 million (£60 million – £70 million).

The Court's ruling

Patent '216 was stable and valid

Notwithstanding that '216 was in force and no validity challenge had been successful or filed at the time of the hearing, Hisun claimed that '216 was invalid due to obviousness, lack of support and ambiguity, and filed a "patent stability analysis report" (issued by Hisun's Chinese patent attorney at the Beijing IP Court to support this claim). The Court refused this argument as the report had been commissioned by Hisun, and therefore this report alone was not sufficient to show that the patent was not stable.

Astellas had the possibility to win

Astellas provided the following evidence to the Court:

1. Hisun claimed their generic product as "the first generic in the country"; and claimed in Hisun 2018 semi-annual report that "More than ten species including micafungin sodium for injection are undergoing drug consistency evaluation in accordance with the 'Technical requirements on consistency evaluation of chemical generic drug (injection) (consultation draft)'."
2. Notarized purchase evidence of Hisun generic product in October 2018.
3. Evidence showing that Hisun generic product was offered in tenders and had already won some tenders.
4. An infringement analysis report prepared by Astellas' Chinese patent attorney claiming that Hisun's generic product fell within the scope of '216.

Hisun argued specifically that Astellas had not proved that the amount of water in Hisun's generic product fell within the scope of '216: claim 1 required water content of 3.4 % or less.

The Court first determined that the issue of water content in Hisun's generic product was the only contention; the remaining technical features in Hisun's generic product fell within the scope of claim 1 of '216. Then, according to the inspection report from the Beijing Physical and Chemical Analysis and Testing Center filed by Astellas, the water content of the infringing product actually measured was 1.04%, that is, it was less than 3.4%. [The infringement analysis report presented by Astellas was not commented at all in the Court's decision, which was consistent with the refusal of the acceptance of the patent stability analysis report issued by Hisun's Chinese patent attorney.] At the same time, however, according to the quality standard issued by Renhe Pharmacy Network Company in respect of the alleged infringing product, the limit of detection of water content should be 1.5%.

There was an emergency in this case

The Court ruled that failure to take preservation measures may lead the respondent to continue to infringe the patent during the remaining protection period, further expanding the consequences of damage based on the following:

- According to Hisun's 2018 annual report, Hisun had made a loss. If the alleged infringement was established, Hisun might be unable to compensate the losses caused by the infringement.
- The evidence showed that the alleged infringing product had been sold directly in some pharmacies, including Renhe Pharmacy Network Company. If a pre-trial injunction was not granted immediately, the scope of the infringement might be expanded, increasing Astella's damages.
- Since the alleged infringing product had a clear price advantage, Hisun's action might cause Astellas' relevant market share to decrease significantly, or reduce the price of Astellas' product. Therefore, damage caused to Astellas was irreparable.

Damages to Astellas were higher than Hisun's

The Court ruled in favor of Astellas as the full-term expiry of '216 was 28 June 2020, about six months from the date of the hearing. If the pre-trial injunction was granted, Hisun only needed to suspend production and sales for six months, which could be recovered after the full-term expiry of '216, and the loss should be foreseeable.

The pre-trial injunction would not harm the public interest

The Court ruled that although Hisun would be prohibited from providing the alleged infringing product, consumers could still purchase Astellas' product, and there were other drugs with similar therapeutic functions to choose from, which would not harm the public interest.

Astellas provided a bond

On 9 December 2019, Astellas provided the Court with a bond of RMB 15 million (£1.7 million).

Observations

My view is the following factors play an important role in the grant of the pre-trial injunction:

- The Beijing Physical and Chemical Analysis and Testing Center filed by Astellas proving the infringement. [It is important to have your report issued by an official testing center.]
- Hisun might be unable to compensate the losses caused by the infringement. [Your opponent's annual report could be your friend.]

- '216 would expire about six months from the date of the hearing. [Yes, and it took nine months for the case to be accepted by the court. Are patentees encouraged to file their request pre-trial injunction closer to the full-term expiry?]
- There are other drugs with similar therapeutic functions. [This may mean that the chance of granting the pre-trial injunction may be reduced if there are few alternatives to the invention.]

Although it is encouraging that the first pre-trial injunction has been granted in China, this may not be very exciting if this can only provide six months' protection to the patentee, notwithstanding that Astellas had suffered from sales infringement for at least 14 months (which should be longer realistically) before the pre-trial injunction was granted, and took Astellas nine months to have the pre-trial injunction request accepted by the Court for hearing. Having said so, grant of pre-trial injunction is not a common practice around the world.

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More moves forward?

Amendments to China's Patent Law

On 3 July 2020, the Chinese National People's Congress (NPC) published the second deliberation draft of the fourth amendments to the Chinese Patent Law (the fourth amendments). **Toby Mak** outlines the changes with his own commentary, at the same time keeping attorneys aware of how the patent laws may still differ from ones they are more familiar with. There are still some striking contrasts – such as one exclusion from patentability, punitive damages, the short limitation period for proceedings and significant penalties for false marking, as well as potential changes in the pharma field reflecting US law (such as term extension and generic drug clearance). Proposed changes to In design law bring more international harmonisation, although the term is only proposed to be extended to 15 years. This article provides an overview of the changes to these fourth amendments for the last five years. While many of the changes in the second deliberation draft are heading in the right direction, some "timely" proposals appear not to have been well thought through, including:

- Adding "first publication for public interest in state emergency or abnormal situation" as an exclusion of non-prejudicial disclosure.
- Adding a complex US-style patent linkage system for drug approval, particularly in an article directed to exclusions from patent infringement.

On 3 July 2020, the Chinese National People's Congress (NPC) published a further draft, for consultation, of amendments to the Chinese Patent Law. This is effectively the fourth draft (but described as the Second Deliberation Draft) of the fourth amendments to the Chinese Patent Law (the fourth amendments) soliciting public comments by the deadline 16 August 2020.

Drafts of the fourth amendments were first proposed by CNIPA in April and December 2015. These were reported in my articles published in the May 2015 and March 2016 issues of the *CIPA Journal*. The second draft in December 2015 had already proposed many changes from the first draft in April 2015.

The draft fourth amendments then stayed dormant for about three years. In January 2019, the NPC issued a "First Deliberation Draft" of the fourth amendments, and has now issued a further draft (the "Second Deliberation Draft"). This article consolidates the proposals in these two "Deliberation Drafts", with comments on the proposals and changes. For ease of reference we have included key proposals in the earlier drafts even though these have not been changed. [The origin of the proposals is indicated: D1 and D2 refer to the first and second drafts of amendments; DD1 and DD2 to the first and second "deliberation drafts" (i.e. third and fourth drafts of amendments).] (My observations are highlighted.)