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What China's Patent Linkage System Means For US Drug Cos.

By **Ruixue Ran, Xiaoliang Chen and Justin Wang**
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Ruixue Ran

Xiaoliang Chen

Justin Wang

The Standing Committee of the National People's Congress of China greenlighted a fourth amendment to the Patent Law of China on Oct. 17, 2020, which introduced a patent linkage system, comparable to the U.S. Hatch-Waxman Act, connecting marketing approval of small-molecule drugs to the resolution of potential patent infringement disputes relating to that drug.[1]

As part of developing this patent linkage system, China has recently introduced measures to address a long-standing issue for innovator drug companies in China: the lack of a legal basis on which to accuse a rival's drug of infringement until after the drug has entered the market.

Under the Hatch-Waxman Act, U.S. law provides innovator companies with this option. Without the ability to bring an infringement claim before a generic launch, a patent owner's innovator drug could suffer irreparable damage to its market position before the patent owner can seek redress.

The amended Chinese patent law, effective June 1, provides rules allowing an opportunity for the parties to resolve infringement disputes ahead of actual acts of infringement. Depending on how these rules are implemented and developed, this could bring a major change to the current landscape of patent disputes between innovator and generic drug companies.

The amended patent law's premarketing enforcement provision has been further developed by several implementing regulations and a recent judicial interpretation related to the implementation of the patent linkage system. As of July 5, the following implementing regulations and judicial interpretation have been released and implemented:

- Implementation Measures for Early Resolution Mechanism for Drug Patent Disputes (Trial), jointly issued and effective on July 4, by the National Medical Products Administration and the China National Intellectual Property Administration;

- Provisions on Several Issues Concerning Application of Laws in Trial of Civil Patent Cases Involving Drug Marketing Review and Approval, issued by the Supreme People's Court on July 4 and effective July 5; and

- Administrative Adjudication Measures for Early Resolution Mechanism for Drug Patent Disputes, issued by the CNIPA on July 5 and effective the same day.

The formal promulgation and implementation of these regulations and judicial interpretation set forth an initial framework for the patent linkage system.

As set out in the above documents, China's patent linkage system comprises some elements similar to the U.S. Hatch-Waxman Act.

This includes (1) a Chinese publication of drug-related patent information, "Patent Information Registration Platform for Listed Drugs,"[2] which plays a role similar to the U.S. Food and Drug Administration's Orange Book; (2) a patent certification regime;[3] (3) preapproval resolution of patent disputes;[4] (4) a nine-month stay of marketing approval of the follow-on drugs triggered by the filing of patent cases at the court or the CNIPA;[5] and (5) decisions on the approval of the follow-on drugs with references to the results of the patent disputes,[6] among others.

This article aims to provide initial insight into this new system and to help international innovator drug companies interested in the Chinese market better prepare for upcoming opportunities and challenges the system may present.

Dispute Resolution Under China's Patent Linkage System

Patent Certifications

The implementation measures stipulate that generic or follow-on drug applicants must certify with respect to potential patent disputes when applying for marketing approval for follow-on drugs. Similar to U.S. practice, the implementation measures provide four types of patent certifications:

- Type 1 certification: There is no patent information related to the registered drug in the Patent Information Registration Platform.

- Type 2 certification: The patent related to the registered drug included in the Patent Information Registration Platform has been terminated or declared invalid, or the applicant of the follow-on drug has obtained a patent license from the patent owner.

- Type 3 certification: The follow-on drug applicant promises that its drug will not be listed before the expiration of the corresponding patent.

- Type 4 certification: The patent related to the registered drug is invalid, or the proposed follow-on drug would not infringe the patent.

Most notably, the Type 4 certification means that the follow-on drug applicant will challenge the patent owner by denying that the follow-on drug falls into the scope of the innovator's patent or asserting the listed patent is invalid.[7] This certification provides a patent holder with the right, for a limited time, to request a preapproval resolution of any disputes regarding the certification of its listed patents.[8]

The Type 4 certification is required to be accompanied by a statement, in the form of a table, comparing the generic drug and the claims of the relevant patent. The follow-on applicant must also provide relevant technical materials.[9] It remains to be seen what level of specificity for the relevant technical materials will be required as part of a Type 4 certification. Follow-on applicants may have incentives to provide vague or incomplete information in order to deter innovator drug companies from challenging the certification.

The innovator drug company must make the decision to seek preapproval dispute resolution on a relatively short time period without the benefit of full information about the generic product in question. This may create a risk for the innovator because Article 12 allows the imposition of monetary penalties where Article 76 is invoked and the innovator company knows or should have known that the relevant patent is invalid or the generic drug does not infringe.

Decisions from the regulators will need to be closely scrutinized to determine the practical requirements imposed on follow-on drug applicants under the Type 4 certification framework.

Although the certifications made by the follow-on applicant are to be published in the Chinese Orange Book,[10] the follow-on applicant is also required to notify the drug marketing authorization holders of their certifications both in paper documents and by email.[11]

Initiation of Preapproval Dispute Resolution

After a Type 4 certification is made, the innovator drug company, an interested party or a follow-on applicant are entitled to bring a lawsuit or administrative adjudication to determine whether the follow-on drug falls under the protection scope of any other's patent rights pursuant to Article 76 of the amended patent law, even in the absence of an actual act of infringement.

The innovator drug company has priority to file a lawsuit or an administrative adjudication under Article 76 of the amended patent law within the prescribed 45-day period. The follow-on applicants can initiate litigation or administrative adjudication only if this 45-day period expires without the innovator drug company commencing an action. Additionally, only a lawsuit or administrative adjudication filed by the innovator drug company within the prescribed time limit can lead to the stay period.

Due to its broad and general similarity to the artificial act of infringement provision of the Hatch-Waxman Act,[12] Article 76 of the amended patent law is sometimes referred as China's artificial act of infringement provision. However, we note that neither "artificial act of infringement" nor "infringement" was mentioned in the language of Article 76, and the judicial interpretation further suggests there can be parallel infringement actions.[13]

That being the case, we believe that a dispute under Article 76 may not simply be considered a variant of infringement disputes and seems more likely to be its own type of proceeding. In any case, implementation rules for disputes under Article 76 will require clarification by future legislation.

Forum Selection for Dispute Resolution

Article 76 of the amended patent law also presents one of the most notable features of China's patent linkage system, providing two parallel approaches to resolve patent disputes, litigation before the courts or administrative adjudication before the CNIPA.

Although such dual-track forum selection might sound unfamiliar to U.S. practitioners, it is anchored in China's practice for resolving patent disputes since the establishment of the patent system back to 1984. According to the Patent Law of China, parties can file a lawsuit before the courts or request patent administration agencies, i.e., local intellectual property administrations, to rule on the dispute when facing infringing activities.[14]

Litigation Route

As in the U.S., bringing patent suits before the courts is a popular option for patent owners in China. The courts in China can hear patent infringement disputes and order damages as well as injunctions as relief.

Also, China has a split system, similar to that in certain jurisdictions, such as Germany, in which infringement issues are heard by the courts, while validity issues are heard by the CNIPA whose decision is appealable to Beijing Intellectual Property Court. Local courts, and, in certain regions, specialized IP courts or IP tribunals,[15] will hear first-instance patent infringement cases. Which local court will have jurisdiction depends on circumstances in each specific case.

Article 76 litigation, however, is distinct from other patent infringement litigation. For example, the judicial interpretation stipulates that the Beijing IP court will hear all Article 76 litigation cases.[16] This rule may help unify and harmonize practices as well as deter local protectionist sentiment that sometimes disadvantages foreign patent owners.

When initiating Article 76 litigation, a key factor for foreign patent owners to consider is the uncertainty in the length of proceedings. For example, if the tribunal deems a case foreign-related,[17] courts are not necessarily bound by the time limits stipulated by the Civil Procedure Law of China.[18] A case may be deemed foreign-related if one of the entities involved is a foreign entity.

Furthermore, judicial appraisals or similar case events are not included in the calculation of the time limits. For such reasons, it is not unusual that patent litigation can last over 12 months before a final judgement notwithstanding the time limits applicable to domestic litigation in China.

Administrative Adjudication Route

Although less well-known outside China, the intellectual property administrations have long been a forum for administrative adjudication of general patent infringement disputes in China. According to CNIPA's annual report, in 2019, the IPA system handled 38,618 cases for patent infringement;[19] the number rose to around 42,000 in 2020.[20]

Before the implementation of the amended patent law, patent infringement cases were not handled by the CNIPA, the IPA of national level but by local IPA branches. In administrative proceedings before the local IPAs, parties are allowed to present evidence and the IPAs will conduct hearings and issue decisions on the infringement issues.

For most cases, the administrative adjudications are required to be concluded within three months after institution, a deadline that can be extended for no more than one month if the case is complex.[21] Time for certain events such as appraisals and stays will not be counted in the time limit.[22]

The adjudication measures stipulate that the CNIPA will handle all the administrative adjudication cases

under Article 76.[23] At the same time, the adjudication measures do not clearly stipulate the time limit of the proceeding, as the measures for patent administrative law enforcement and the relevant provisions issued by the CNIPA can be applied to other aspects that are not provided in the adjudication measures.[24]

Article 76 administrative adjudication should also be completed within the time limit stipulated in the measures for patent administrative law enforcement — that is, within three months for general cases or four months for complex cases.

One of the most noteworthy factors for considering the Article 76 adjudication route is that the adjudicative decision made by the CNIPA is not necessarily final, because it can be appealed to the Beijing IP court and then further appealed to the Supreme People's Court.

Takeaways for Innovator Drug Companies

Limitations on Article 76 Litigation and Article 76 Administrative Adjudication

According to Article 76 of the amended patent law, within the prescribed time limit, the National Medical Products Administration may decide whether to suspend the approval of relevant drug marketing applications based on the effective judgment of the people's court.

But under the implementation measures, an administrative adjudication made by the CNIPA under Article 76 is given the same status as a judgement made by the people's court. Such an administrative adjudication can also be used as the basis for the National Medical Products Administration to determine whether to suspend the approval of relevant follow-on drug marketing applications.[25]

This is significant because, normally, the possibility of obtaining an effective judgment in China within nine months for a civil case, under which Article 76 litigation is categorized, is relatively low. Therefore, when it appears likely that a follow-on drug will be found infringing, an innovator drug company may want to choose Article 76 administrative adjudication instead of Article 76 litigation, in order to rapidly block the approval process of the follow-on drug marketing applications.

Neither Article 76 litigation nor Article 76 administrative adjudication is without risk. For example, Article 12 of the judicial interpretation stipulates that the follow-on drug applicant may seek monetary remedies against the patent owner when the latter initiates an action under either pathway and when the innovator knows or should know that the asserted patent is invalid or not infringed.

The scope of how the phrase "knows or should know" requires interpretation in specific cases. At this point, it appears that the burden is on the generic applicant to show that the innovator drug company knew or should know the patent was invalid or not infringed. Whether that burden is met may depend on the specificity of information the innovator drug company possess when it makes the decision to proceed with an Article 76 proceeding.

Limited Length of Stay on Marketing Approval

The stay on marketing approval for the follow-on drugs triggered by the filing of Article 76 litigation or administrative adjudication is limited to nine months.[26] In comparison, the stay period is up to 30 months in the U.S.

Therefore, when the course of the proceeding of an Article 76 litigation or administrative adjudication is longer than nine months, the National Medical Products Administration may approve the follow-on drug after the stay period even if the corresponding Article 76 litigation or administrative adjudication is still pending.

Whether Injunctions Can Be Requested

The judicial interpretation stipulates that, where the injunction request complies with the relevant provisions of the Patent Law and the Civil Procedure Law, a patent owner or interested party may obtain a preliminary injunction to ban the follow-on drug applicant from manufacturing, using, offering to sell, selling or importing corresponding products for commercial purpose within the validity period of the relevant patent.[27]

In other words, even if the approval procedure of the follow-on drug marketing application cannot be blocked because the judgment of the Article 76 litigation fails to take effect within the stay period, a preliminary injunction from the court may nonetheless provide useful relief.

Even in the event the National Medical Products Administration issues the approval, the innovator drug company may be able to obtain an ultimate finding of infringement faster than would be possible without Article 76. Because Article 76 administrative adjudication does not provide a basis for seeking preliminary injunctions, this relief would not be available.

Strategy for Electing Length of Proceedings

The different schedules for litigation and administrative adjudication provide innovator companies with some ability to control the pace of resolution of infringement claims. The adjudication measures provide that the patent owner has priority to initiate proceedings following the drug marketing application. The patent owner therefore has the ability to elect either litigation, if longer proceedings are preferable, or administrative adjudication, if a shorter proceeding is more advantageous.

Parallel China and U.S. Proceedings

Where parallel proceedings concerning the same drug and similar patented technology are ongoing in both China and the U.S., the innovator company and its counsel need to compare and coordinate case strategy, timelines and milestones in different jurisdictions in order to make decisions on a global basis. In such a situation, having a quick and favorable resolution on the merits in one jurisdiction may provide negotiating leverage in other jurisdictions.

Accordingly, to determine how to resolve the disputes under Article 76, we recommend that patent owners consider how the forum selection under Article 76 will affect the global resolution of the disputes. Moreover, it is always essential in complex multijurisdictional litigation to evaluate the impact of tactical and strategic decisions in each forum and how those decisions may be used adversely in other proceedings.

Ruixue Ran is a partner, and Xiaoliang Chen and Justin Wang are advisers, at Covington & Burling LLP.

Covington partners Michael Kennedy and John Balzano, of counsel Sheng Huang, and associate Andrew Wang, contributed to this article.

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[1] This article focuses on the legal framework applicable to small-molecule drugs, and references to "drugs" in this article are intended to refer exclusively to small-molecule drugs. Biologics follow different procedures.

[2] See Arts. 2, 3, 4, 5, 12 and 15 of the Implementation Measures.

[3] See, Arts. 6, 12 and 15 of the Implementation Measures.

[4] See Art. 7 of the Implementation Measures.

[5] See Art. 8 of the Implementation Measures.

[6] See Arts. 9 and 10 of the Implementation Measures.

[7] See Art. 6 of the Draft Implementation Measures.

[8] See Art. 7 of the Implementation Measures.

[9] See Art. 6 of the Implementation Measures.

[10] See Arts. 6 and 12 of the Implementation Measures, the China Orange Book was launched online on May 18, 2021 via the following link: https://zldj.cde.org.cn.

[11] See Art. 6 of the Implementation Measures.

[12] See 35 U.S.C. § 271(e)(2)(A).

[13] See Art. 11 of the Judicial Interpretation.

[14] See Art. 60 of the Patent Law of China (1984).

[15] https://www.cov.com/-/media/files/corporate/publications/2018/03/establishing_15_-ip_tribunals_nationwide_chinese_courts_further_concentrate_jurisdiction_over_ip_matters.pdf.

[16] See Art. 1 of the Judicial Interpretation.

[17] See Art. 270 of the Civil Procedure Law of China.

[18] The Civil Procedure Law generally requires six months for concluding first-instance cases and three months for concluding appellant cases. These are extendable under certain circumstances. See Arts. 149 and 176 of the Civil Procedure Law of China.

[19] https://www.cnipa.gov.cn/art/2020/1/23/art_250_150169.html.

[20] https://www.cnipa.gov.cn/art/2021/1/28/art_499_156468.html.

[21] See Chapter 2, Section 3(2) of the Guidelines for Handling Administrative Adjudications on Patent Infringement Disputes.

[22] See Art. 21 of the Measures for Patent Administrative Law Enforcement (2015 Revision).

[23] See Art. 2 of the Adjudication Measures.

[24] See Art. 22 of the Adjudication Measures.

[25] See Art. 9 of the Implementation Measures.

[26] See Art. 8 of the Implementation Measures.

[27] See Art. 10 of the Judicial Interpretation.