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Patent Linkage in China: Up, Running and with Chinese Characteristics

As one of the most significant IP developments in China, the Fourth Amendment to the PRC Patent Law introduced patent linkage for pharmaceutical patent litigation in China.[1] A full set of rules implementing the patent linkage system has finally been released and immediately came into force in the first week of July. These rules will likely incentivise both innovators and generic companies and further shape their regulatory, litigation and competitive strategies. The patent linkage system is designed with marked Chinese characteristics, taking into account the existing practices and judicial economy of patent litigation as well as broader healthcare policy imperatives in China. Generic competition will, in all likelihood, be intensified in light of the patent linkage litigation.

China's patent linkage system

Article 76 of the amended PRC Patent Law provides for a cause of action for early resolution of patent disputes between an innovator and a generic company. In essence, the dispute is to determine whether a generic drug falls within the scope of an innovator's patent shortly after the generic company files its drug application. The parties may submit a "scope confirmation determination" either to the China National Intellectual Property Administration (CNIPA) or to the Beijing IP Court. Article 76 provides, at a high level, that the PRC drug authority, National Medical Products Administration (NMPA), may decide whether to stay approval of a generic drug application in light of the outcome of the administrative or court determination.

With the set of the rules implementing Article 76 now fully in force, the patent linkage system is officially up and running in China. The patent linkage rules are:

1. the patent linkage measures jointly issued by the CNIPA and NMPA (**Measures**) regarding the interplay between regulatory review and patent law;
2. the judicial interpretation issued by the Chinese Supreme Court (**Judicial Interpretation**) concerning the court's adjudication of scope confirmation actions; and
3. the administrative rules issued by the CNIPA (**Administrative Rules**) concerning the administrative proceedings for scope confirmation.

Key highlights of the patent linkage rules

Compared to the draft rules released for public comment, the newly implemented rules have adopted a number of critical changes clarifying how the patent linkage system may actually work. We summarise the key and noteworthy highlights below.

1. Both innovators and generic companies are subject to affirmative obligations.

To utilise the patent linkage system, both innovators and generic companies are required to take certain acts.

As China has already established its version of the Orange Book, an innovator first needs to disclose its patents on the Approved Drug Patent Registration Platform (**Platform**).[2] A generic drug applicant subsequently must make one of the following certifications with respect to each patent listed for a reference drug:

– Type I Certification: no relevant patent is listed on the Platform.

[1] Please see our earlier alert regarding the Fourth Amendment to the PRC Patent Law: https://www.allenovery.com/en-gb/global/news-and-insights/publications/china-patent-law-amendment-brings-sea-change-to-pharmaceutical-patent-regime.

[2] The Approved Drug Patent Registration Platform can be accessed through https://zldj.cde.org.cn/home (in Chinese). According to Article 5 of the Measures, only compound patents, composition patents and indication patents can be registered on the Platform.

– Type II Certification: the patent listed was invalidated or has expired or was licensed to the generic.

– Type III Certification: the generic drug will not enter the market until patent expiration.

– Type IV Certification: the patent is invalid or the generic drug otherwise does not fall within its scope.

In the previous consultation draft for public comment, a generic company had no obligation to provide its certification to the innovator of the reference product. Article 6 of the Measures now makes it clear that a generic company would not only be required to do so but also to provide proof if it elects to make a Type IV Certification. Such proof includes claim charts as well as other related technical materials. Notably an innovator will in turn be required to submit the generic's proof when it files the scope confirmation action with the CNIPA or the Beijing IP Court.

Finally, the innovator has 15 days to notify the generic company and the NMPA upon filing the scope confirmation action.

2. It is now or never for an innovator to obtain a nine-month regulatory stay to slow generic entry.

The key mechanism under the patent linkage rules is a nine-month regulatory stay period set by the NMPA upon receiving the notification regarding the scope confirmation action filed by an innovator.

Article 8 of the Measures clarifies the effect if an innovator does not pursue a scope confirmation action under Article 76 of the Patent Law. The innovator will waive its right to trigger the regulatory stay period and to object to the generic drug application. In such circumstances, the NMPA may proceed with approving the generic drug application based on the technical review result and the generic company's certification.

This means that in order to delay the generic approval process, it would be critically important for an innovator to actively seek the regulatory stay by instituting a scope confirmation action.

3. Seeking administrative determination by the CNIPA could be generally more favourable to innovators.

A commonly asked question before the implementation of the patent linkage system: How could any scope confirmation determination possibly be made and become effective within the nine-month regulatory stay period in China? This is a legitimate question as, given the already significant backlog in the court system, patent proceedings currently take much longer than nine months to conclude, particularly taking account of the time to go through the appeal process before the court issues a final judgment.

The solution proposed under Article 9 of the Measures is to give the same weight to the CNIPA determination as that of an effective court judgment if determination is sought through the judicial route with the Beijing IP Court. In other words, the action the NMPA will take, upon the expiry of the stay period, hinges on an effective court judgment or an administrative determination made by the CNIPA. This design is likely driven by the fact that a scope confirmation determination is relatively straightforward and is generally less susceptible to overturn on appeal.

Importantly, Article 9 of the Measures provides that where the NMPA does not receive an effective court judgment or a CNIPA determination, it could proceed with the regulatory approval of the generic drug application. As only in rare circumstances it would be possible for an effective court judgment to be issued within a nine-month period, seeking an administrative determination by the CNIPA would seem generally more favourable to innovators.

More specifically, according to Article 9 of the Measures, where an administrative determination is sought with the CNIPA and the CNIPA finds that a generic drug application is caught by an innovator's patent within the nine-month period, the NMPA will only approve the generic drug application upon expiry or invalidation of the patent. Conversely, the NMPA can approve the marketing of the generic drug where the CNIPA concludes that the generic drug application does not impinge on the innovator's patent.

4. Patent validity is key to thwarting the generic entry efforts.

As most patent linkage litigation likely involves a parallel patent invalidation proceeding, the validity of a patent is similarly unlikely to be finally disposed of within the nine-month stay period. The CNIPA presides over the invalidation proceeding and its decision has to be reviewed by the courts to take effect and become final unless the parties choose not to go through judicial review.

Article 9 of the Measures provides that the NMPA will approve a generic drug application if the patent is "legally adjudicated invalid". At the time of writing, it is unclear what "legally adjudicated invalid" means. In particular, neither the CNIPA nor the NMPA has provided any clarification as to whether "legally adjudicated invalid" means "finally adjudicated invalid" or "declared invalid by the CNIPA". The distinction is significant and could have a direct impact on the generic entry landscape in China. It is at least questionable to what extent innovators' interest and rights are sufficiently protected if generic drugs are allowed to be marketed where patent validity is still being litigated and reviewed by the courts.

In any event, patent validity is undoubtedly the most important battle for innovators to thwart and delay the generic entry.

5. First-to-market exclusivity incentivises aggressive, early generic entry.

The patent linkage regime awards a 12-month market exclusivity period to a first-to-market generic. Article 11 of the Measures specifies that such exclusivity is available to the first generic company that "files a Type IV Certification and successfully invalidates the patent based on its Certification and subsequently obtains market approval".

In recent years, Chinese generic companies have been particularly aggressive in filing invalidations against innovators' patents, including compound patents, long before the patent expires. This has been driven in part by the broader healthcare reform efforts ranging from procurement to pricing which are all designed to lower drug prices in China. This generic entry trend is likely to continue and may even be exacerbated in light of a further marketing exclusivity incentive provided under the patent linkage system.

6. Potential damages claim against an innovator's bad faith assertion.

While the rules and case law with regard to patent abuse are less developed in China, Article 12 of the Judicial Interpretation creates a patent abuse claim by a generic company against an innovator. Specifically, a generic company could sue an innovator for damages where the innovator brings a scope confirmation action despite the fact that it "knows or should have known" that its patent should have been invalidated or that the generic drug does not fall within its patent.

It is apparent that the new cause of action against an innovator's bad faith assertion is to prevent the system from being overrun with patent linkage cases as well as meritless and problematic tactics to delay the generic entry. However, what constitutes an actual or constructive knowledge in the context of Article 12 is unclear, particularly considering the nature of patent validity determination, which is highly factually specific and legally complex. It is also unclear what damages a generic company could claim and how that could be assessed if the damages cover the losses allegedly caused by the regulatory stay.

A potential damages claim on the basis of an innovator's bad faith assertion undoubtedly adds a further layer of complication to the patent linkage system. It highlights the need for coordinating parallel proceedings in different jurisdictions to ensure that no statement made in a foreign proceeding can be unwarrantedly used by a generic company to aid its patent abuse claim in China.

What are the possible scenarios for generic entry in China?

With its goal of streamlining the patent disputes between innovators and generic companies, the patent linkage system is intended to facilitate early generic entry where a generic drug application does not come into conflict with an innovator's patent. However, where a generic drug has been determined to fall within the scope of the innovator's patent and where such determination can be sought within the nine-month stay period, it may be possible to further delay the generic entry, depending on whether the patent can sustain a validity challenge.

We illustrate below the three most likely scenarios for future generic entry in China.

STRONG CASES: No generic entry before patent expiry	**MOST CASES:** Early generic entry upon invalidation of the patent	**WEAK CASES:** Early generic entry upon the expiry of the nine-month stay period
– Innovator obtains a favourable determination in the administrative proceeding within nine months – Defeat the generics' validity challenge(s) – No generics will receive marketing authorisation prior to patent expiry	– Most generic drugs likely fall within the scope of the innovators' patents – Whether a generic drug can be launched early depends on whether the patent can be invalidated	– Generic proceeds to approval after patent linkage litigation which will be concluded within the nine-month period – Patent validity does not matter in these cases; so long as the generic drug does not fall within the scope of the patent, generics will generally be cleared for approval

Strategic planning is key

While the newly issued rules to some extent clarify the operation of the patent linkage system that is already up and running in China, there remain many important nuances and details that need to be further fleshed out or even litigated in the years to come. Needless to say, the actual patent linkage litigation and associated strategies will differ significantly from case to case.

It should be noted that the patent linkage system not only reflects the commitment China made in the US-China Phase 1 trade deal, but also is an integral part of the ongoing healthcare reform in China. Planning and strategising for patent linkage litigation therefore requires an early, holistic and practical assessment taking into account the full competitive landscape as well as potential pricing and procurement implications.

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