How China's Patent Linkage System Will be Implemented

- The patent linkage system intends to resolve drug patent disputes between originators and generic drug applicants in the early stages
- The Chinese drug patent linkage system does not apply to drug patents that are not recorded in the Chinese Orange Book
- The regulatory approval stay only applies to a patent protection scope dispute claim under a Category 4 Statement

Ting Wu of Haiwen & Partners raises some questions to highlight how China's newly implemented drug patent linkage system attempts to resolve drug patent disputes in the early stages, which will have a sweeping impact on market entry strategies for chemical drugs in China.

The newly launched Chinese drug patent linkage system, the so-called Drug Patent Dispute Early Resolution Mechanism, links Chinese drug marketing authorizations to the patent status of an originator's brand name drugs. This system intends to resolve drug patent disputes between originators and generic drug applicants in the early stages through a judicial or an administrative proceeding before the relevant generic drugs are approved for marketing with the aim of striking a balance between protecting originators' brand name drugs and promoting generic drugs of high quality.

In 2017, the Chinese Central Government announced that it would introduce a drug patent linkage system in China, and subsequently amended the PRC Patent Law (中华人民共和国专利法) in 2020 to codify the drug patent linkage system. In accordance with the PRC Patent Law, on July 4, 2021, the PRC National Medical Products Administration (NMPA) and China National Intellectual Property Administration(CNIPA) jointly issued the Implementing Measures for the Mechanism for the Early Resolution of Pharmaceutical Patent Disputes (Trial Implementation) (Patent Linkage Measures) (药品专利纠纷早期解决机制实施办法 (试行)), which came into force on the same day.

To further support the implementation of the drug patent linkage system, on July 5, 2021, the PRC Supreme Court issued the Provisions on Several Issues on the Application of the Law Concerning the Trial of Civil Disputes over Patents of Pharmaceuticals Applying for Registration (关于审理申请注册的药品相关的专利权纠纷民事案件适用法律若干问题的规定) to specify the judicial proceedings for the drug patent linkage system; and CNIPA issued the Measures for the Administrative Rulings in Connection with the Mechanism for Early Resolution of Pharmaceutical Patent Disputes (药品专利纠纷早期解决机制行政裁决办法) to clarify the administrative proceedings for the drug patent linkage system.

The highlights of the Patent Linkage Measures are discussed in more detail below.

1. **What is the "Chinese Orange Book" under the Chinese drug patent linkage system and what drug patents are eligible to be listed in this book?**

NMPA is responsible for establishing and maintaining the "Chinese Orange Book" (also known as the Chinese Marketed Drug Patent Information Record Platform). Originators (i.e., drug marketing authorization holders (MAH) may voluntarily list the following drug patent information in the Chinese Orange Book within 30 days after receiving market authorization from NMPA, and must update any changes to such information within 30 days upon the occurrence of such changes:

- Chemical drugs: patents claiming active pharmaceutical ingredients (API) compound, compositions containing API and drug indications;
- Biologics: patents claiming sequence structure of active ingredients; and
- Traditional Chinese Medicines (TCM): patents claiming compositions, medicinal herb extracts and indications.

The Chinese drug patent linkage system does not apply to drug patents that are not recorded in the Chinese Orange Book. Notably, patents claiming intermediates, metabolites, crystal forms, manufacturing methods or testing methods are explicitly excluded from being listed in the Chinese Orange Book. This means, originators are encouraged to develop core patents for their drugs.

2. **What statements are generic applicants required to make upon generic applications?**

Chinese drug patent linkage system requires generic applicants to make one of the following statements on each of the applicable drug patents listed in the Chinese Orange Book upon their submission of generic drug applications with NMPA.

- Category 1: No applicable patent is listed in the Chinese Orange Book. NMPA may grant market approval at its discretion after ANDA technical review.
- Category 2: Applicable listed patent has expired or was invalidated; or the generic applicant has obtained a license from the applicable patent right owners. NMPA may grant a market approval at its discretion after ANDA technical review.
- Category 3: The generic applicant undertakes not to market its generic drug prior to the expiration of the applicable listed patent.
- Category 4: The generic applicant believes that the applicable listed patent will be invalidated or the generic drugs does not fall within the protection scope claimed by the applicable listed patent.

Generic applicants are required to notify MAHs of originator drugs (or the patentee in cases where MAH is not the patentee) of the statements made by them even though the Patent Linkage Measures do not impose a timeline for generic applicants to notify MAH in a timely manner. Instead of waiting for the notifications from generic applicants,

patentees or MAHs of originator drugs are also recommended to monitor generics statements, which are published by NMPA within 10 working days after its acceptance of the corresponding ANDA applications.

3. **How can a patentee or MAH of a brand name drug respond to a Category 4 Statement?**

In general, within 45 days (not working days) from the date of disclosure or publication of the relevant generic application by NMPA, the patentee or MAH of a brand name drug, may either file a lawsuit with the Beijing IP Court (i.e., initiating a judicial proceeding) or file an opposition with CNIPA (i.e., initiating an administrative proceeding) against a Category 4 Statement as to whether the concerned generic drug falls within the protective scope of the applicable listed patents. Further, within 15 working days after the initiation of the foregoing judicial or administrative proceedings, the patentee or MAH of a brand name drug must notify NMPA of the proceeding initiated by it. These actions will trigger a regulatory approval stay as will be discussed further in part four below.

It is worth noting that a patent invalidation proceeding under a Category 4 Statement would not trigger a regulatory approval stay. The regulatory approval stay only applies to a patent protective scope dispute claim under a Category 4 Statement, i.e., whether the concerned generic drug falls within the protective scope of the applicable listed patent.

If a patentee or MAH of a brand name drug, for any reason, does not take judicial or administrative action within the aforesaid 45-day period, NMPA may grant market approval for that generic drug at its discretion after ANDA review. Alternatively, in this scenario, a generic drug applicant may also file a lawsuit with a PRC court or file a complaint with CNIPA to request the court or CNIPA to confirm that its generic drug does not fall within the protective scope of the applicable listed patent.

4. **What happens if the patentee triggers a regulatory stay for an ANDA application?**

With respect to ANDA applications for chemical drugs, NMPA, upon its receipt of a notice of the initiation of judicial proceedings or administration proceedings by the patentee or MAH of a brand name drug, will stay the regulatory approval of the corresponding ANDA application for up to nine months. This nine-month stay would not affect the ANDA review process, but NMPA will stay the market approval for the affected generic drug during the nine-month period. This nine-month regulatory approval stay can only be applied once.

If a patentee receives a favorable decision from a court or CNIPA within nine months, NMPA will only grant an ANDA approval for the generic drugs upon the expiration of the applicable listed patent. NMPA will resume its ANDA approval process if:

i. the patentee cannot obtain a favorable decision from a court or CNIPA,
ii. the parties settle the case within nine months,
iii. the applicable listed patent has been invalidated; or
iv. there is no valid court or CNIPA decision within the 9-month stay period (this is a likely scenario because judicial proceedings concerning a complex drug patent dispute usually takes more than nine months).

It should be further noted that the nine-month regulatory stay does not apply to TCM generics and biosimilar applications. For TCM generics and biosimilars, no matter whether such drugs would fall within the protective scope of the applicable listed patent, NMPA may grant market approval at its discretion after its technical review even though TCM generics and biosimilar MAHs are not expected to market their TCM generics and biosimilars prior to the expiration of the applicable listed patents. If in any case TCM generics and biosimilars MAHs market their TCM generics and biosimilars prior to the expiration of the applicable listed patents, the patentees may resort to a PRC court or CNIPA for any patent infringement dispute.

5. **What is the market exclusivity right for a chemical generic applicant who has successfully challenged a listed patent based on a Category 4 Statement?**

A generic chemical applicant, who receives the first ANDA approval for a chemical drug from NMPA and who is the first one to successfully challenge the applicable listed patent, is entitled to a market exclusivity right with a period up to 12 months provided that such a market exclusivity period does not exceed the term of the listed patent being challenged.

During such a market exclusivity period, NMPA will stay the ANDA approval of other similar generic chemical drugs except for the drugs of co-challengers.

Commentary
Undoubtedly, this newly established Chinese patent linkage system will have a sweeping impact on market entry strategies for (both innovative and generic) chemical drugs in China. Innovative and generic drug applicants are advised to proactively and comprehensively evaluate and assess their patent prosecution and enforcement strategies, as well as regulatory and product market access strategies at an early stage.

There are many questions concerning the implementation of this newly established Chinese patent linkage system that are yet to be answered, such as how to interpret the "double first" concept for market exclusivity designation and how to define co-challengers. It remains to be seen to what extent patentees or MAHs of brand name drugs can leverage the Chinese patent linkage system to resolve potential patent dispute at an early stage.

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