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China's National Medical Products Administration Proposes Implementing Rules on Patent Linkage for Public Comments

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The National Medical Products Administration (NMPA) recently published the draft Measures for Implementing an Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "**Draft Measures**"). The agency is soliciting public comments through October 25, 2020. The Draft Measures provide an operating mechanism for the NMPA and the China National IP Administration (CNIPA) to link generic drug applications to pharmaceutical patent protection ("**Patent Linkage**").

The most recent amendment to the Chinese Patent Law describes the general principles of patent linkage, but lacks operational details. The Draft Measures are intended to answer these operational questions. Contrary to the U.S. Hatch-Waxman Act which provides a mechanism for generic companies to challenge patent exclusivity, the Draft Measures describe a framework for originators to defend their patent exclusivity. If the originators fail to defend their patent exclusivity in time, the NMPA will not be obligated to withhold generic drug approvals. This fundamental difference in the regulatory philosophy may shape the competitive landscape in favor of generic companies in the future.

The highlights of the Draft Measures are summarized below.

1. The Chinese Orange Book.

The Draft Measures indicate that the NMPA will launch an information disclosure platform, i.e., the *Approval Drug Patent Registration Platform*, for patent holders to list their product-related patents for generic companies' awareness. This platform will serve a similar purpose as the U.S. Orange Book.

The Chinese Orange Book will include composition of matter patents, formulation patents, and method of use patents with respect to chemical drugs.

2. Certifications of Generic Companies.

Generic drug applicants must make one of the following four types of certifications as to each patent listed in the Chinese Orange Book with respect to the reference drug product when submitting the marketing authorization application. Such application will be published by China's Center for Drug Evaluation (CDE) in the public domain. These four types of certifications are similar to the certifications under the U.S. Hatch-Waxman Act.

a. Type I Certification: No relevant patent is listed in the Chinese Orange Book.

b. Type II Certification: The listed patent has expired or was invalidated.

c. Type III Certification: The generic drug will not enter the market before the expiration of the listed patent.

d. Type IV Certification: The listed patent is invalid or will not be infringed by the commercialization of the generic drug.

3. Triggers of Patent Litigation and Approval Stay

Under the U.S. patent linkage system, the generic drug applicant must notify the originator/patentee if it made the Paragraph IV certification. The originator has the right to sue the generic drug applicant immediately on receipt of

the notice letter. If the originator/patentee files an infringement claim within 45 days, the FDA may not grant final approval of the generic application for 30 months from the originator/patentee's receipt of the notice letter.

The proposed Chinese patent linkage system is different. It expects the originator/patentee to actively monitor the generic applications published by the CDE. Upon discovery of generic applications and certifications, if the originator/patentee disagrees, the originator/patentee will need to file an infringement claim with the court or the CNIPA within 45 days after the CDE's publication, and must submit a copy of the case acceptance notification to the CDE within 10 days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. Moreover, the NMPA's approval stay is only nine months, and the technical review does not need to stay in this nine-month period. If the originator/patentee cannot secure a favorable court judgment or a decision from the CNIPA within the nine-month period, the NMPA can grant marketing authorization to the generic applicant after the nine-month period expires. This marketing authorization will be irrevocable.

Biosimilar applications are not subject to the proposed patent linkage system in China. The NMPA can proceed with the technical review and marketing authorization upon receiving biosimilar applications. To delay the entry of biosimilars, the originator/patentee will need to file an infringement claim with the court or CNIPA within 45 days after the CDE's publication of the biosimilar application, and secure a favorable decision before the NMPA's issuance of the marketing authorization. The NMPA will then convert the marketing authorizations into a conditional approval effective after the relevant patents expire.

4. Marketing Exclusivity

The first generic applicant with a Type 4 certification will be granted a marketing exclusivity period for up to 12 months from the date of marketing authorization, and the exclusivity will not exceed the originator's patent term. During this exclusivity period, the NMPA will not approve other generic applications, but the agency can continue to accept and review generic applications.

The proposed Draft Measures will cement the patent linkage system in China. Innovative pharmaceutical companies are advised to carefully review the Draft Measures and propose their comments to the NMPA before the deadline in order to effectively protect their commercial interest.