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## China's Latest Patent Law Amendment Introduces Patent Linkage, Patent Term Extension, and Patent Term Adjustment

On July 3, 2020, the Standing Committee of the National People's Congress published the second draft amendment to the Patent Law (the "Second Draft Amendment"), soliciting public comments on this bill through August 16, 2020. Notably, the Second Draft Amendment, compared with the previous draft amendment published in January 2019 (the "First Draft Amendment"), revises and expands on several provisions to enhance protection for new drugs.

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Patent term extension/restoration ("PTE") first appeared in the First Draft Amendment, and is reinforced in Article 42 of the Second Draft Amendment with some substantive changes to the statutory wording. Article 42 provides that the China National IP Administration (CNIPA) can restore a maximum of 5 years to the invention patent of a new drug obtained a marketing authorization approval in China to compensate commercialization delays caused by regulatory review and approval upon the request of the patent holder; and the total patent term shall not exceed 14 years after the new drug is launched.

While the First Draft Amendment limits the scope of the PTE to "innovative new drug" that have not been marketed in China or overseas, Article 42 of the Second Draft Amendment uses the phrase "new drug" instead without further qualifying or defining what constitutes as a "new drug," the scope of PTE under the Second Draft Amendment could be interpreted more broadly to cover Class 1 innovative new drugs and Class 2 improved new drugs. The definition of new drug remains to be clarified by the legislature and regulators.

Article 42 of the Second Draft Amendment also incorporates the concept of patent term adjustment ("PTA"). Under Article 42, the patent term of invention patent can be adjusted to compensate for unreasonable delays due to patent examination carried out by the patent administrative authority. However, the calculation method for PTA needs to be further clarified by the legislature and regulators, especially for the determination of "unreasonable delays."

Another highlight of the Second Draft Amendment is the newly added Article 75 on patent linkage, which addresses China's commitment in the 2020 US-China Economic Trade Agreement.

1. *Legal challenge by the originator/patent holder.* The originator/patent holder or interested party can file a complaint with the CNIPA or a PRC court within 30 days after the National Medical Products Administration (NMPA) announces the submission of a marketing authorization application made by a generic drug applicant. The patent holder can also file an appeal within 15 days after the issuance of CNIPA's administrative decision. Conversely, if the patent holder fails to file the initial complaint within the prescribed timeframe, the generic drug applicant may apply for PRC court's or CNIPA's official confirmation that the relevant technologies involved are not infringing on any patents of the originator drug as listed and disclosed on a web-based publication platform listing approved drug patents (i.e. the Approved Drug Patent Registration Platform).
2. *Regulatory review and administrative appeal.* The NMPA will follow the outcome of the patent litigation or the administrative adjudication when granting the marketing authorization to generic applicant, provided that (a) the judicial or administrative decision is issued within 9 months after the case acceptance date of the complaint filled by the originator/patent holder; and (b) the generic *chemical* drug candidate has passed technical review which forms part of the regulatory review of the generic's marketing authorization application.
3. *The establishment of coordination between drug and patent administrative authorities.* The Second Draft Amendment mentions in general terms that a mechanism of coordination between the CNIPA and NMPA should

be established to come up with detailed implementation measures on how to implement the patent linkage system.

While parallels can be drawn between the Second Draft Amendment and the US patent linkage regime (such as the similar patent term extension provisions), the Second Draft Amendment presents many uncertainties and notable differences from the US patent linkage system:

- *The scope of the PTE.* As aforementioned, what constitutes a “new drug” for PTE under the Second Draft Amendment remains to be further clarified.
- *Regulatory review stay.* It is unclear, under Article 75, whether a 9-month regulatory review stay (i.e., suspension of regulatory review and approval process of the generic chemical drug) will automatically apply while the patent litigation/administrative case is pending. Furthermore, Article 75 is silent on whether the NMPA has discretion to grant the marketing authorization approval to the generic applicant if the patent challenge case has been pending for more than 9 months. In the US, if the patent holder sues the generic applicant for infringement within 45 days upon notice, the FDA is prohibited from approving the generic application for 30 months or until the generic applicant wins the patent litigation, whichever occurs first.
- *Patent status referral source.* Although the concept of the Approved Drug Patent Registration Platform from the Second Draft Amendment resembles the FDA Orange Book, it is unclear whether the Approved Drug Patent Registration Platform will serve as a separate registry that lists drug patent information only; or, whether this platform will be connected to, and synchronized with the Catalogue of Approved Drug, an online registry launched in 2017 that identifies drugs that have been approved in China and contains the related drug commercial and registration information.
- *Market exclusivity and other issues.* Under the US patent linkage system, the United States Patent and Trademark Office can grant a 180-day market exclusivity to the first generic applicant that successfully challenges the validity of the originator’s patent. The Second Draft Amendment is silent on this point as well as other issues such as data exclusivity.

PTE and patent linkage system represent the Chinese government’s intent to balance innovation and affordability. Pharmaceutical companies should take the opportunity to submit comments on the Second Draft Amendment before the deadline, and closely monitor the legislative developments.