

## China Draft Patent Law Amendment Introduces Initial Framework for Patent Linkage for Pharmaceutical Patents and Patent Term Adjustment and Restoration

July 14, 2020

Patent Litigation

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On July 3, 2020, the Standing Committee of the National People's Congress (“**NPC**”) of China published a second draft amendment (the “**Draft**”) on the Patent Law of the People's Republic of China (“**Patent Law**”). Most notably among the Draft's proposed 29 revisions to the Patent Law, the Draft includes high-level provisions that would establish a framework for early resolution of pharmaceutical patent disputes between patentees and interested parties of approved drug products and applicants for follow-on drug products,<sup>1</sup> often referred to as a patent linkage system. Specifically, the Draft includes new provisions that could create a jurisdictional basis—both for civil and administrative proceedings—for early resolution of patent infringement disputes involving a marketed drug product, and might establish a nine-month stay of approval of the follow-on application while the patent dispute is being adjudicated. The Draft also introduces high-level provisions that would establish patent term adjustment (“**PTA**”) and, for “invention patents of new drugs,” patent term restoration (“**PTR**”) regimes.

The Draft is the first legislative development regarding the Patent Law since the conclusion of the Economic and Trade Agreement between the United States and China on January 15, 2020 (“**Phase One Trade Agreement**”), which contained substantial content on patent protection for pharmaceuticals, including related to patent linkage, PTR, and PTA (see our client alert [here](#)). Although there are a number of ambiguities in the Draft and much detail remains to be addressed in implementing regulations and judicial interpretations, the Draft, if finalized, could bring substantial changes to pharmaceutical patent litigation in China. The NPC is accepting comments on the Draft until August 16, 2020.<sup>2</sup>

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<sup>1</sup> The Draft uses the undefined term “drug” throughout the patent linkage provisions in Article 75. It is therefore ambiguous whether both small molecule and biological drug products would fall within the proposed framework. It is also ambiguous whether only generic and biosimilar applicants would be subject to the proposed patent linkage framework, or whether other innovator product applicants that potentially infringe the patent of a marketed drug product would also fall within the framework's scope. For purposes of this client alert, the general term “follow-on” is used to refer to potentially infringing generic, biosimilar, and innovator applicants and their proposed products.

<sup>2</sup> <http://www.npc.gov.cn/flcaw/userIndex.html?lid=ff80808172b5fee8017313b6232c2b55>

## Proposed Patent Linkage System

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The Draft proposes to add three new paragraphs to the patent infringement exception clause in new Article 75 of the Patent Law, which together would establish a high-level patent linkage framework in China.

First, proposed paragraph 2 of Article 75 provides that if a patentee or interested party believes that a marketing application for a follow-on drug product falls within the scope of patents listed on the Patent Information Registration Platform for China Listed Drugs (“**Patent Registry**”), the patentee or interested party can seek adjudication of the patent infringement claim. This can be done either by filing a lawsuit in a People’s Court or by requesting that the patent administrative agency of the State Council (*i.e.*, China National Intellectual Property Administration (“**CNIPA**”)) issue an administrative ruling on infringement.<sup>3</sup> The infringement action may be initiated within 30 days from the date the drug administrative agency of State Council (*i.e.*, National Medical Products Administration (“**NMPA**”)) announces the follow-on application. If the patentee or party-in-interest fails to file a lawsuit or request an administrative ruling within those 30 days, the follow-on applicant may request that a People’s Court or CNIPA confirm that the drug does not fall within the scope of patents listed on the Patent Registry.

This provision could provide a jurisdictional basis for patentees and interested parties, as well as follow-on applicants, to resolve potential patent disputes based on the filing of a follow-on application with NMPA.<sup>4</sup> Ambiguities remain, however, about the scope of the cause of action proposed under paragraph 2 and how a patentee or interested party will be able to determine whether a follow-on application potentially infringes the patent(s) listed on the Patent Registry.<sup>5</sup>

Second, proposed paragraph 3 of Article 75 provides that NMPA may make a decision on whether to approve the follow-on application<sup>6</sup> based on a judgment of the People’s Court or CNIPA that is issued within nine months of when the patentee or party-of-interest’s infringement adjudication request was accepted. If not satisfied with the administrative ruling, the patentee or

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<sup>3</sup> Chinese patent law provides both judicial and administrative procedures for patentees seeking remedies against infringement: patentees or parties-in-interest can choose whether to bring civil infringement actions in People’s Courts or to file complaints with CNIPA.

<sup>4</sup> The act of filing a follow-on application might not be viewed as a “sale,” “offer to sell,” “manufacture,” or “import,” which forms the basis for a patent infringement action under current Article 11 of the Patent Law, and the manufacture or import of a disputed drug for the purpose of obtaining marketing approval might otherwise be considered immune from a patent infringement claim under current Article 69 of the Patent Law (also known as China’s Bolar Exemption). See Beijing People’s High Court’s decision in Case (2018) Jing Min Zhong No. 474. See also Paragraph 1 of Article 11 and Item (5) of Article 69 of Patent Law.

<sup>5</sup> For example, the Draft does not specify what information about a pending follow-on application will be published and whether or how that information differs from the information that is currently available about pending marketing applications (e.g., application number, applicant name, drug name, application type, date of receipt).

<sup>6</sup> The Draft appears to limit this provision to marketing applications for “chemical” drugs. It is unclear whether this limitation is intentional, particularly given that the more general term “drug” is used throughout the rest of the proposed patent linkage provisions.

interested party may file a lawsuit with the People's Court within 15 days from the date of receiving the administrative ruling.

Although not clear on its face, this provision appears intended to establish a nine-month stay of approval of the follow-on application by NMPA, presumably during which time the patent dispute can be resolved by a People's Court or CNIPA. Under current law, NMPA is not required to wait for a court judgment before granting its final approval of a follow-on application. This approach could bring greater regulatory predictability to patentees and interested parties as well as follow-on applicants, but there are many ambiguities in the Draft that will need to be addressed to make the proposal cohesive and effective in practice.<sup>7</sup>

Finally, proposed paragraph 4 of Article 75 explicitly directs NMPA to work with CNIPA to jointly formulate specific patent linkage measures and to implement those measures once they are approved by the State Council. Collaboration between NMPA and CNIPA is crucial to developing an effective patent linkage system.

## Proposed PTA and PTR Regimes

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The Draft proposes two new paragraphs to Article 42 of the Patent Law that, at a high level, would establish PTA and PTR regimes in China.

New paragraph 2 of Article 42 provides that if an invention patent is granted after four years from the filing date of the invention patent application and after three years from the date of requesting substantive examination, the patentee may request "compensation" for unreasonable delay not caused by the applicant. This provision appears intended to provide PTA to invention patent applicants. New paragraph 3 of Article 42 provides that the State Council may make a decision to extend the duration of "invention patents of new drugs" that have been approved by NMPA to make up for the time used for drug approval, i.e., PTR.<sup>8</sup> The extension must not exceed five years, and the overall patent term after market entry of the new drug must not exceed fourteen years.

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These proposed amendments to the Patent Law will be further refined through implementing regulations, guidelines, and judicial interpretations of the Supreme People's Court. Further guidance as to the details of the high-level procedures in the Patent Law will be key for establishing a robust patent linkage system and comprehensive PTA and PTR in China. We encourage stakeholders to closely monitor these frameworks throughout and subsequent to the legislative process to enact the Patent Law.

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<sup>7</sup> For example, it is unclear under this provision how NMPA should treat a pending follow-on application if a decision by a People's Court or CNIPA is not rendered within nine months, or during the judicial review of an administrative decision that was unfavorable to the patentee or interested party.

<sup>8</sup> It is unclear whether the extension accounts for both the time spent by NMPA to review the drug application for approval and the development time associated with the drug.

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