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China's Newly Approved Amendment to Patent Law Changes the Landscape of Patent Litigation

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Patent and ITC Litigation

Recently, the Standing Committee of the National People's Congress of China approved an amendment to the Patent Law.[1] The amended Patent Law is slated to take effect on June 1, 2021. Most notable among the 29 amended provisions are changes to rules for patent litigation. Below are some highlights that we believe may particularly interest international companies having patent dispute concerns in China.

Enhanced Remedies for Patent Right Holders (Article 71)

The amended Patent Law adds several measures to enhance remedies. Statutory limitations on patent damages have frequently been cited as a factor discouraging patent owners from pursuing relief through the patent system. The approved amendment significantly extends these limitations. For example, paragraph 3 of Article 71 introduces a provision for punitive damages, which allows the court to award a multiple of damages, up to five times, in case of willful infringement. Also, paragraph 2 of the same article allows the court to impose statutory damages at the court's discretion between RMB 30,000 (US$ 4,479) to RMB 5 million (US$ 746,469) where it is difficult to determine actual damages under a rubric either of losses incurred to the right holder, gains obtained, or reasonable license fees. This is a dramatic increase from the range of statutory damages allowed by the old Patent Law (between RMB 10,000 and RMB 1 million).

Last but not least, the amended Patent Law codifies an existing judicial interpretation allowing a burden-shifting process to encourage the disclosure of financial information.[2] Under applicable discovery rules in China, parties are not automatically compelled to produce discovery, including financial information that may be necessary to determine the measure of damages, unless they are specifically ordered to do so by the courts through issuance of a document production order. The approved amendment allows the court to order the defendant to provide financial information. If the defendant fails to do so, the court may make an inference about the extent of damages based on the plaintiff's claim and evidence. This is expected to deter parties from withholding relevant financial information in its possession, and improving the ability of patent owners to obtain recovery in excess of statutory damages where they have suffered losses, or an infringer has obtained gains, in excess of statutory limits.

[1] *Patent Law of the People's Republic of China (2020 Amendment)*, approved on October 17, 2020.
[2] Article 27 of *Interpretation (II) of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases*.

Early Resolution of Pharmaceutical Patent Disputes (Article 76)

Article 76 of the amended Patent Law provides high-level provisions that would establish a framework for early resolution of pharmaceutical patent disputes between patent right holders/interested parties of approved drug products and applicants for follow-on drug products. Specifically, this article provides a jurisdictional basis for initiating litigation during the approval process of follow-on drug products. Implementation rules, including related to a stay of marketing approval while the patent dispute is being adjudicated,[3] are to be formulated by the National Medical Products Administration ("NMPA") and the National Intellectual Property Administration ("CNIPA"), and then reported to the State Council for approval.

Patent Term Extension Regime (Article 42)

The amended Patent Law also establishes for the first time a patent term extension regime. Other jurisdictions that provide for a patent term based on the original filing date allow for the extension of a patent term based on delay during the patent office. 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 patent right holder may request "compensation" for unreasonable delay that was not caused by the applicant. An analogous provision exists specifically for drug applications, where paragraph 3 provides that the NMPA shall compensate for the time used for drug approval upon the patent holder's request for patent term compensation, and the compensation must not exceed 5 years and the total patent term after market entry of the new drug must not exceed 14 years.

Patent Abuse and Antitrust (Article 20)

Article 20 of the amended Patent Law addresses antitrust issues in connection with patent rights. This article provides that the application and enforcement of patent rights shall be in line with the "bona fide" principle and no abusive actions of patent rights that eliminate or restrict competition shall be allowed. This guiding principle has been developing in Chinese law for several years, in particular to ensure that dominant market participants do not seek to use patent law to improperly suppress competition. Article 20 introduces this concept directly into the patent law for the first time.

Other new measures in the amended Patent Law that may be of interest to firms with intellectual property concerns in China include, but are not limited to extending the term for design patents from 10 years to 15 years (Article 42), confirming a part of a product as allowable subject matter for design patents (Article 2), and introducing an open-licensing regime (Articles 50 to 52).

We recommend all parties with interests in intellectual property rights in China to keep updated with the development of relevant implementation rules and evaluate the impact of those changes on their business.

[3] The length of the stay of marketing approval is not explicitly provided in the amended Patent Law.

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