COVINGTON

China's Draft Patent Law Includes Important Enhancements to Patent-Owner's Rights

January 10, 2019

Patent and ITC Litigation

On January 4, 2019, the Standing Committee of the National People's Congress ("NPC") of China published a draft amendment to the Patent Law (the "Draft") for public comment. While this draft is not yet final, it indicates China is taking concrete steps to help patent holders with the exercise of their rights. The Draft was previously approved by the State Council on December 5, 2018 after soliciting public comments in 2015[1], and then passed to the Standing Committee of the NPC for deliberation[2]. The NPC is accepting comments on this revised draft until February 3, 2019[3].

Since its promulgation, the Patent Law of China has experienced three rounds of major amendments in 1992, 2000 and 2008. According to the official explanation from the NPC[4], the goals of this fourth amendment include: 1) enhancing the protection for the legitimate rights and interests of the patentees; 2) facilitating the implementation and use of the patents; and 3) legalizing those practices that have been proven to be mature. Based on the specific measures in the Draft, once in force, this amendment can reasonably be expected to create a more friendly environment for patentees than in the past. Below are some highlights from the Draft that we believe may particularly interest international companies having patent concerns in China.

- **Enhanced remedies for patent right holders.** Establishing an infringer's illegal profits has always been difficult in China, mostly due to the lack of compulsory evidence exchange to allow assessment of the infringer's financial information. The current Patent Law addresses this by allowing the court to impose statutory damages where it is difficult to determine actual damages (e.g., the losses incurred to the patentee, or the gains obtained or a reasonable royalty to be paid by the infringer). The statutory damages according to the current Patent Law are set at the court's discretion between RMB 10,000 (US$ 15,652) and RMB 1 million (US$ 157,480). Responding to concerns that these amounts are insufficient to remedy all forms of patent infringement, Article 72 of the Draft dramatically increases the upper limit to RMB 5 million (US$ 787,400) to better allow patent damages to reflect legitimate expectations of patent rights-holders.

[1] See "China's Draft Patent Law Seeks Five Fold Increase on Damages Cap for Patent Infringement Cases"
[2] http://www.sipo.gov.cn/zscqgz/1134384.htm
[3] http://www.npc.gov.cn/npc/flcazqyj/2019-01/04/content_2070155.htm
[4] http://www.npc.gov.cn/COBRS_LFYJNEW/user/UserIndex.jsp?ID=13137851

Article 72 also allows the court to award a multiple of damages, up to five times, in cases of willful infringement. In this regard, the Draft stipulates that a willful infringement must reach a "serious degree," which is expected to be further defined in subsequent legislation and judicial interpretations.

The Draft also codifies an existing judicial interpretation allowing a burden-shifting process to encourage the disclosure of financial information.[5] Specifically, to deter a defendant from withholding financial information in its possession, Article 72 allows the court to order the defendant to provide financial information and, 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.

- **Drug patent term extension regime.** Article 43 of the Draft also includes patent term extensions designed to compensate for the administrative assessment and approval time spent on launching an innovative drug. The extension is at the discretion of the State Council and is subject to two restrictions: that the extension shall not exceed five years and the total patent term after the launch of the innovative drug shall not exceed fourteen years. This regime was first mentioned by the former China Food and Drug Administration ("CFDA")[6, 7], and then greenlighted by the General Office of the CPC Central Committee and the General Office of the State Council[8]. In this Draft, more details about the regime are specified which appears similar to the U.S. system in certain respects.[9]

  Notably, the Draft does not specifically mention implementation of a patent linkage system, which observers of China's IP system have been expecting to see codified soon. It seems that some concrete (e.g., the procedure of China ANDA challenges) and technical provisions (e.g., how to define an artificial infringement occurred when a generic drug is seeking an administrative approval) may possibly be defined in subsequent judicial interpretations or corresponding amendments to the Implementing Regulations of the Patent Law or the Guidelines for Patent Examination.

- **Bona fide principle and Antitrust.** Article 20 of the Draft 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 explicit emphasis on antitrust can be viewed as China's continuing effort to balance between legitimate expectations of patent rights-holders and the public interest through antitrust issues. China has been a leading jurisdiction at analyzing and engaging the intersection of patent and antitrust law since a series of high profile SEP cases in 2013.

- **Open-licensing regime.** Article 50 of the Draft introduces an open-licensing regime to promote the implementation and use of patents. This system references the mature practice in other jurisdictions like the UK, France and Germany. Under this regime, a patentee may submit a written declaration to the China National Intellectual

---

[5] 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.*
[6] CFDA was renamed as National Medical Products Administration, or "NMPA" in 2018.
[7] See *Relevant Policies for Encouraging Innovations of Drugs and Medical Devices and Protecting Innovators' Rights and Interests for Public Comment* issued on May 12, 2017.
[8] See *Opinion on the Promotion of Reformation regarding Examination and Approval System as well as Innovation of Pharmaceutical Products and Medical Devices* issued on October 8, 2017.
[9] *35 U.S.C § 156.*

Property Administration ("CNIPA") that he is willing to license anyone to exploit the patent and specifies the payment method and the license fee. The CNIPA shall thereafter make an announcement and implement an open license. Further details of this regime are recited in Articles 50-52, including but not limited to the mechanism for withdrawal of the open-licensing statement, the acquisition of the license, and the mediation of relevant disputes.

Other changes in the Draft include strengthening the inventor's rights and interests (Article 6), strengthening the establishment of a patent information public service system (Article 22), excluding means of nuclear transformation from patentable subject matter (Article 26), allowing the claim of priority rights for design patents (Article 30), optimizing the procedure for claiming priority right (Article 31), extending the term for design patents from 10 years to 15 years (Article 43), enhancing patent administrative enforcement proceedings (Articles 69 and 70), and clarifying liabilities for internet service providers (Article 70).

It remains to be seen how these provisions may evolve or change in response to public comment, but based on the status of the Draft patentees may expect greater opportunity from these potential changes to China's patent system. We recommend all parties with interests in intellectual property rights in China to keep updated with the development of the law, evaluate the impact of these changes on their business, and consider submitting comments as early as possible ahead of the deadline.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Patent and ITC Litigation practice:

Ruixue Ran	+86 10 5910 0511	rran@cov.com
Justin Yijun Wang	+86 10 5910 0318	jwang@cov.com
Andrew Di Wang	+86 10 5910 0313	adwang@cov.com
Sheng Huang	+86 10 5910 0515	shuang@cov.com
Robert Williams	+86 21 6036 2506	rwilliams@cov.com