



WHITE PAPER

November 2020

China Promulgates Fourth Amendment to Patent Law

On October 17, 2020, the Standing Committee of the National People's Congress in China promulgated the fourth amended Patent Law of the People's Republic of China, which came into force in its original form in 1985, with subsequent amendments in 1992, 2000, and 2008. The amendment will come into effect on June 1, 2021.

The amendment for the first time codifies certain notable changes for pharmaceutical-related patents, including the introduction of a patent linkage system in China to align with international practices.

In addition, the amendment (i) increases statutory damages, introduces punitive damages, and shifts the burden of proving damages in patent infringement actions; (ii) enables the China National Intellectual Property Administration to determine patent infringement disputes of significant national impact; (iii) expands the scope of protection over design patents (particularly on subject matter) and extends their term of protection; (iv) allows disclosure under a national emergency or an extraordinary state of affairs that is not novelty-destroying; and (v) allows patentees to file a declaration to implement open license.

With the amendment, patent lawsuits concerning generic drug applications may be instituted under the new patent linkage system and more design patent applications may be filed in view of the expanded scope of protection and the extended term of protection to 15 years. The increase in the amount of statutory damages, the introduction of punitive damages and the shift of burden in proving damages in patent infringement actions may motivate patentees to enforce their patent rights before courts in China. It is expected that Chinese authorities will continue to refine the existing legal regime to put the amendment into action and practice.

The following highlights several key changes brought by the fourth amended Patent Law of the People's Republic of China.

INTRODUCTION

On October 17, 2020, the Standing Committee of the National People's Congress in China promulgated the fourth amended Patent Law of the People's Republic of China (the "Amended Patent Law"), which came into force in its original form in 1985, with subsequent amendments in 1992, 2000, and 2008. The Amended Patent Law will come into effect on June 1, 2021, with a view to strengthen the protection of legitimate rights and interests of patentees, to promote the implementation and application of patent rights in China, and to refine the overall patent grant mechanism in response to the ever-changing patent usage environment in the past decade and the increase in demand for patents from domestic and foreign enterprises.

NOTABLE CHANGES FOR PHARMACEUTICAL-RELATED PATENTS

The enhanced scope of patent protection offered by the Amended Patent Law represents notable progress for pharmaceutical-related patents. In line with the draft Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) ("Draft Implementation Measures") recently released by the National Medical Products Administration ("NMPA") and the China National Intellectual Property Administration ("CNIPA"), the Amended Patent Law provides for patent term adjustment and introduces the long-awaited patent linkage system in China.

PATENT TERM EXTENSION AND ADJUSTMENT

Article 42 of the Amended Patent Law provides for patent term extension to compensate for the delays caused by regulatory review and approval of a new drug. At the request of the patentee, CNIPA may grant a compensation term for patents covering a new drug that has been approved for marketing in China. The compensation term shall not exceed five years, and the total effective patent term after the new drug is approved shall not exceed 14 years. Further clarifications are needed on what constitutes a "new drug" and whether patent term extension is available for drugs approved prior to the effect of the Amended Patent Law.

Article 42 of the Amended Patent Law further allows CNIPA to, at the request of the patentee, adjust the term of an invention patent to compensate for unreasonable delays in the patent examination process, except those caused by the applicant. Such an adjustment is available only when the patent is granted after at least four years from the filing date, and at least three years after the request for substantive examination was filed.

PATENT LINKAGE SYSTEM

Similar to the Hatch-Waxman Act in the United States, Article 76 of the Amended Patent Law introduces a patent linkage system for early resolution of patent disputes concerning generic drug applications.

The amendment provides a legal basis for commencing offensive actions against a generic drug applicant during a new drug application in cases where a patentee or a stakeholder believes that such a drug application falls within the patent scope. The patentee or stakeholder can file a lawsuit before a court or a request for administrative adjudication before CNIPA. The drug applicant may also institute a declaratory judgment action of non-infringement.

The amendment further provides that NMPA may suspend its approval process for the new drug application if the generic drug is found to fall within the patent scope. The suspension may apply pursuant to an effective court judgment, subject to the time limit to be prescribed by NMPA. Although the Amended Patent Law is silent on whether the approval process would be suspended pursuant to a court's appealable decision or CNIPA's decision of infringement, the Draft Implementation Measures have made it clear that non-final decisions can still trigger the suspension, wherein the approval process will not resume until the decisions become final.

The patent linkage system is intensified by the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Drug Marketing Review and Approval of Patent ("Provisions") issued by the Supreme People's Court for public comments on October 29, 2020. The Provisions set forth rules for adjudicating patent linkage dispute cases, and

designate Beijing Intellectual Property Court as the sole court to hear patent linkage disputes in the first instance.

INCREASING STATUTORY DAMAGES AND INTRODUCING PUNITIVE DAMAGES

Article 71 of the Amended Patent Law increases the amount of statutory damages that can be awarded to a patentee. With the amendment, Chinese courts may ascertain the amount of compensation to be awarded in a patent infringement action on the basis of either the actual losses incurred to the patentee or the gains obtained by the accused party from the infringing activities, instead of resorting to the latter when the former is not available as in the existing provision. If it is difficult to determine both the infringer's gains and the patentee's losses, multiples of reasonable patent royalties may be referred to determine the damages award. Where all of the above are difficult to determine, Chinese courts may award statutory damages; the minimum amount has been increased from RMB 10,000 to RMB 30,000 and maximum amount has been increased from RMB 1 million to RMB 5 million.

Article 71 of the Amended Patent Law further introduces punitive damages for the purpose of deterrence. For any intentional infringement of patent rights, if the circumstances are serious, the amount of compensation could be one to five times the amount ascertained by the court on the basis of the losses incurred to the patentee, the gains obtained by the accused party, or multiples of reasonable patent royalties for the disputed patent. The introduction of punitive damages aligns with the Civil Code of the People's Republic of China (effective January 1, 2021), which allows the rights holder to be awarded punitive damages for any intentional infringement of intellectual property. In fact, punitive damages relating to intellectual property have been widely considered by Chinese leaders in recent years, and relevant rules have been added to a number of Chinese laws and guidelines, including the third and fourth amended Trademark Law of the People's Republic of China in 2013 and 2019, the Guidelines on Determination of Damages and Statutory Damages in Disputes over Intellectual Property and Unfair Competition released by the Beijing Higher People's Court on April 21, 2020, and the draft amendment of the Copyright Law of the People's Republic of China released on April 30, 2020.

SHIFTING THE BURDEN OF PROVING DAMAGES TO ACCUSED PARTIES

In contrast to traditional civil procedure rules where the plaintiff has the burden to submit evidence showing damages in patent infringement actions, Article 71 of the Amended Patent Law provides a potential shift of the burden of proof to the accused party. With the amendment, a Chinese court may order the accused party in a patent infringement action to submit financial books and materials to evidence the gains obtained from infringement; if the accused party refuses to comply, the court could determine damages based on evidence adduced and claims raised by the patentee. As suggested by a few precedents, the new rule helps lower the patentees' burden of proof that has been aggravated by the lack of discovery process in China and may potentially increase the amount of damages awarded to patentees.

ENABLING CNIPA TO HANDLE PATENT INFRINGEMENT DISPUTES OF SIGNIFICANT NATIONAL IMPACT

In China's bifurcated patent enforcement system, patentees may, instead of filing a lawsuit with a competent court, initiate an administrative patent infringement action with administrative authorities. Under existing provisions, such administrative authorities are offices under market supervision administrations at the provincial or municipal levels. According to Article 70 of the Amended Patent Law, CNIPA is, for the first time, empowered to handle patent infringement disputes that have "significant impact nationally" at the request of patentees or other interested parties.

Administrative patent infringement actions have been increasingly attracting attention from patentees because they are generally adjudicated much faster than typical court proceedings. In these kinds of actions, evidence preservation and injunctions are normally available, although there is no damages award and its decision is subject to judicial review. Unlike local administrations, CNIPA has its own patent examiners with profound expertise in almost every sector of technology, who are capable of fairly adjudicating patent infringement disputes. However, it remains to be seen how "significant national impact" will be defined in detailed regulations and be determined in practice.

Article 69 of the Amended Patent Law stipulates the measures that patent administrations may take in handling patent passing off and patent infringement disputes, which include interrogation of relevant parties, on-site investigation, and inspection of products related to the accused illegal activities.

EXPANDING AND EXTENDING PROTECTION OVER DESIGN PATENTS

Under Article 2 of the Amended Patent Law, subject matters of a design patent have been expanded to include new designs of portions of a product. This enables applicants to protect their unique design features more conveniently without being limited by commonplace features of the same product. For example, a graphic user interface patent may no longer include the product (e.g., a mobile phone or a computer) on which the graphic user interface is displayed. In addition, Article 42 of the Amended Patent Law has extended the term of a design patent from 10 years to 15 years. This is part of China's effort to join the Hague Agreement and to facilitate Chinese applicants to protect their designs worldwide.

China outperforms any other country in terms of the number of design patent applications filed each year. In 2019, about 712,000 design patent applications were filed in China, approximately 97.2% by domestic applicants. There have been 2.72 million valid design patents in China as of August 31, 2020. It is expected that the amendment may lead to further proliferation of design patents, especially since Chinese design patents are not subject to substantive examination, and more concerns about reduced freedom to operate and increased likelihood of infringement disputes may arise. Among the 5,505 decisions on patent infringement cases issued by Chinese courts in the four-year period of 2013–2016, approximately 62.9% (3,462) were design cases.

In addition, Article 29 of the Amended Patent Law has provided for “domestic priority” of design patents. Before the amendment, the right of priority can only be claimed to earlier Chinese invention patent or utility model patent applications, and the later patent application should be filed within 12 months from the filing date of the invention patent or utility model patent application on which the priority claim is based. Such “domestic priority” is often used by applicants to add new subject matters or change the type of application

between inventions and utility models. With the amendment, prior design patent applications can also serve as a basis for claiming domestic priority within six months after its filing date, thereby providing a new tool for applicants to improve their design applications.

ALLOWING DISCLOSURE UNDER NATIONAL EMERGENCY OR EXTRAORDINARY STATE OF AFFAIRS

Situations where prior disclosure does not destroy novelty of a later-filed patent application on the same subject matter have already been provided for in Article 24 of the existing Patent Law. Article 24 of the Amended Patent Law expands the scope of protection to cover inventions disclosed in the case of a national emergency or any extraordinary state of affairs, with the grace period remaining six months before the filing of a patent application.

In the midst of the COVID-19 pandemic, this addition may help protect the novelty of pharmaceutical-related patents if the inventions have to be disclosed as soon as they are developed, considering that a significant number of provinces in China treated COVID-19 as a “particularly significant public health emergency” and adopted a first-level action plan against it.

ALLOWING IMPLEMENTATION OF OPEN LICENSE

Articles 50 to 52 of the Amended Patent Law introduce a patent open license system. In China, the commercialization rate of technology achievements is only around 10%, significantly lower than the 40% seen in some developed economies. In this regard, the patent open license system aims to reduce transaction costs and improve the efficiency of patent licensing.

Where a patentee voluntarily files a written declaration to CNIPA that it is willing to license its patent to any entity or individual and specifies the method and standard for license fees, CNIPA will make an announcement to implement an open license. Any entity or individual can obtain the license by sending a written notice to the patentee and paying the prescribed license fees. The patentee can also file a written

announcement to withdraw the open license without affecting the validity of granted licenses. To file an open license declaration concerning a utility model and design patent, a patent evaluation report issued by CNIPA is needed to endorse the validity of the patent.

In order to encourage participation in the open license system, participating patentees will be entitled to a reduction or exemption to annual fees for open licenses. If the parties have disputes over an open license and fail to settle among themselves, the parties may request mediation from CNIPA or file a lawsuit before Chinese courts.

Other amendments brought by the Amended Patent Law include encouraging enterprises to implement and use patented inventions while sharing the income with inventors or designers properly; codifying the Principle of Good Faith against filing of junk patents and malicious patent infringement actions; codifying pre-suit injunction, evidence preservation, and property preservation against accused parties; and adjusting certain provisions in accordance with recent changes of other laws and regulations such as extension of the statutory limitation period from two years to three years.

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