



## WHAT DOES THE THIRD AMENDMENT TO CHINA'S PATENT LAW MEAN TO YOU?

Since its enactment in 1984, China's Patent Law ("the Patent Law") has been amended three times: first in 1992, then in 2000, and most recently in 2008. The first amendment added pharmaceutical compositions to the list of patentable subject matter and inaugurated China's membership in the Patent Cooperation Treaty. The second amendment was intended to bring the Patent Law into compliance with the Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPS").

The widely expected and long-awaited third amendment to the Patent Law was passed by the National People's Congress on December 27, 2008, and will go into effect on October 1, 2009. This *Commentary* discusses several significant changes to the Patent Law brought by the third amendment ("Amendment") and their potential impact on patent protection in China.

### HEIGHTENED PATENTABILITY STANDARD—ADOPTION OF ABSOLUTE NOVELTY

Article 22.2 of the current Patent Law has a blended novelty standard for patentability—in assessing novelty of an invention, one considers publication anywhere in the world but not public use or knowledge outside of China. This blended novelty standard occasionally allows "patent hijacking," *i.e.*, the patenting in China of another's invention witnessed at a public event (such as a trade show) outside of China. The Amendment replaces this blended novelty standard with an absolute one and defines "prior art" as *publicly known art anywhere in the world before the filing date*.

This new novelty standard applies across the board to all three categories of patents: invention patents, utility model patents, and design patents. Therefore, this

new patentability standard will have a significant impact on the way in which patent validity is challenged in China. For example, under the current law, public use outside China does not destroy novelty and is, therefore, irrelevant in invalidation proceedings. Under the new law, however, it will be highly relevant, as will evidence of overseas public sale, public dissemination, and public knowledge.

Moreover, the adoption of an absolute novelty standard will have the effect of reducing patent hijacking. The Amendment does not state whether and to what extent this absolute novelty requirement would be made retroactive to previously granted patents or pending applications. If so, the Amendment would make prior art significantly more available for challenging the validity of existing Chinese patents.

## CLARIFICATION OF DOUBLE PATENTING

As mentioned, China has three types of patents: invention patents, utility model patents, and design patents. A Chinese invention patent is similar to a United States utility patent and protects a new technical solution relating to a product, a process, or an improvement thereof. An invention patent has a 20-year term. A Chinese utility model patent, on the other hand, covers a new technical solution relating to a product's shape, structure, or a combination thereof. A utility model patent has a 10-year term. Utility model patents are not substantively examined and are granted after formality examination, which generally takes about one to one-and-a-half years or less. In contrast, invention patents are substantively examined and can take three to five years to grant. Therefore, it is advantageous to have early issuance of a utility model patent to sue for infringement or to serve as a deterrent, in addition to or in substitution for an invention patent.

It has been a widespread practice of patent applicants to obtain invention patents and utility model patents on the same inventions, although such a practice has been frowned upon by courts. Therefore, some double patenting has occurred in China. This practice continued until the State Intellectual Property Office ("SIPO") amended its Patent Examination Guidelines to limit its occurrence in July 2007.

The Amendment substantially adopts the 2007 SIPO approach and stipulates that the same invention can only be granted one patent at any given time. While the same

applicant can file an application for both invention patent and utility model patent directed to an identical invention on the same day, the invention patent can be granted only when the applicant declares his intention to abandon the previously granted utility model patent if such utility model patent has not lapsed.

However, ambiguities still exist. For example, it is not clear whether the prohibition against double patenting applies only to same-invention double patenting (*i.e.*, applications with identical claims), or whether it also applies to obviousness-type double patenting (*i.e.*, applications with different yet patentably indistinguishable claims). Furthermore, it is not clear whether a genus claim and species claim will be considered as double patenting.

## IMPROVEMENTS ON DESIGN PATENTS

The Amendment in amended Article 23 introduces an absolute novelty standard in assessing the novelty of a design. Moreover, a patentable design must possess a prominent difference from prior art designs and combinations thereof. In other words, design patents will be subject to the same novelty standard as invention patents. It also appears that a new design must not be obvious over prior art. This is a welcome change because SIPO currently does not impose, in practice, an obviousness standard in determining the patentability of design patents. This lack of an obviousness standard in practice, coupled with a narrow novelty standard, has resulted in many "junk" design patents being issued in China.

In addition to raising the patentability standards for designs, the Amendment no longer allows the registration of trademarks and labels as design patents. The combination of these changes in effect plugs many of the loopholes widely used in China by some applicants who register other parties' marks as design patents and use the design patents as shields against enforcement by the trademark owners. After October 1, 2009, it is expected that fewer junk design patents will be applied for and granted.

Another change brought by the Amendment is that an offer for sale is an infringing act under the amended Patent Law, enabling patentees to pursue claims of infringement at trade fairs or wholesale markets.

## **TOUGH DISCLOSURE RULES FOR INVENTIONS RELYING ON “GENETIC RESOURCES”**

China is rich in genetic resources, and the Chinese government supports and encourages research to lawfully develop intellectual property derived from these assets. For inventions that rely on genetic resources, the Amendment for the first time imposes a requirement that the patent applicant disclose in the application the direct source of the genetic resources. In addition, the applicant must disclose the original source of the genetic resources or provide a reason explaining why he is unable to do so, if the original source cannot be identified. The prospective patentee must also prove that the access to such genetic resource was lawfully obtained.

The Amendment also stipulates that no patent shall be granted to inventions that rely on genetic resources if the acquisition or use of the underlying genetic resources violated Chinese law or regulation. These changes reflect discussions held at the Convention on Biological Diversity (“CBD”) and were adopted after consultation by the Chinese government with other biologically diverse countries, as well as discussions with the United States and other countries that were concerned about introduction of CBD-related concepts into patent examination.

The impact of these provisions will largely depend on how “reliance” on “genetic resources” is defined and what constitutes illegal acquisition and use. The Amendment does not provide a definition of “genetic resources,” nor does it limit “genetic resources” to those in China only. According to CBD, “genetic resources” means genetic material of actual or potential value, and “genetic material” refers to any material of plant, animal, microbial, or other origin containing functional units of heredity. China’s interest in protecting genetic resources needs to be balanced with its interest in providing certainty in patent grants, encouraging development of a biotech R&D sector, and pursuing cooperative arrangements with other countries that reflect the risks involved in biotechnology research. Until the scope of these provisions is clarified in the Implementing Regulations and examination guidelines (the revision of which is under way by SIPO at the time of this writing), prudent companies will want to make sure that the genetic resource on which the completion of the invention relies is subject to proper access and benefit-sharing mechanisms.

Biotechnology companies need to pay close attention to this disclosure requirement because failure to comply could result in either the denial or invalidation of a Chinese patent. It should be noted that there is no equivalent requirement in the patent laws of Europe, Japan, or the United States.

## **HEAVY PENALTY FOR FOREIGN FILING WITHOUT A LICENSE**

As international companies set up research and development centers in China, they need to consider where first to file patent applications for inventions completed in China. Today, Article 20.1 of the Patent Law requires that a Chinese patent applicant for an invention completed in China must first file a patent application in China before any foreign filing. However, the current law is silent about what a foreign applicant is required to do in the same situation. Consequently, some foreign-owned research labs in China circumvent the first-to-file requirement of the current Patent Law by assigning patent applications for inventions completed in China to one of its foreign entities and then having the patent applications filed outside of China first in the name of that foreign entity.

The Amendment provides that patent applications for inventions completed in China may be filed directly outside of China (*i.e.*, in the United States) without the need of first filing in China (as prescribed under the current law). However, prior to filing outside of China, applicants should submit the invention to SIPO for review for the purposes of protecting State secrets. Violation of the review requirement will result in loss of patent rights in China. SIPO is drafting Implementing Regulations for the new Patent Law, and it expects that the procedure for the State secret review would be set out in the Implementing Regulations; however, it is expected based on current discussions that the submission for the review would not involve disclosure of the invention to the degree required for patent filing.

Finally, although there is no statutory definition for inventions “completed in China,” the understanding is that inventions jointly made in China by Chinese inventors and non-Chinese inventors are subject to this requirement.

## CLARIFICATION OF PATENT JOINT-OWNERSHIP RIGHTS

As multinational companies enter into research collaborations with Chinese universities and companies, they need to understand how Chinese law governs the commercialization of jointly developed and owned patent rights. In that regard, the Amendment includes provisions that govern unilateral exploitation of the patent rights without the consent of joint owners.

Specifically, the Amendment states in new Article 15 that unless otherwise agreed upon, a joint owner can individually exploit or allow another to exploit the patent by means of a general license, but must share the royalties obtained thereof with other joint owners. The Amendment does not stipulate how the royalties are to be distributed. Consent by all joint-owners is required for other means of exploiting the jointly owned patent. Under such rules, multinational companies should draft collaborative research agreements in ways to ensure that commercial use of the patent rights arising from the joint research efforts will not be blocked by the default veto power of the joint owner(s).

## ROAD MAP FOR COMPULSORY LICENSES

No compulsory license has ever been granted in China by SIPO, even though Chapter VI of the current Patent Law contains compulsory license provisions and China implemented the Doha Declaration through a National People's Congress decision on accession as well as through SIPO's Measures for the Compulsory Licensing of Patents Relating to Public Health Issues ("Pharmaceutical Compulsory Licensing Measures"). The Amendment provides a more definitive statutory basis to compel compulsory licenses, implements the Doha Declaration into the Patent Law, and contains new rules that restrict the general scope of compulsory licensing while making it more feasible and likely for compulsory licenses to be granted in the area of pharmaceuticals (new Article 50) and semiconductor technology (new Article 52).

China has long provided a working requirement in its Patent Law. Under the current Patent Law, compulsory licensing may be granted where an entity is unable to obtain a license on reasonable terms and conditions within a reasonable

period of time. The Amendment, however, restricts the scope for compulsory licensing to the standard 1) that the patentee has not exploited or has not sufficiently exploited the patent rights without any reasonable grounds within three years since the date that patent rights were granted and four years since the date of filing, or 2) if the patentee exploits the patent in a manner determined to be an "act of antitrust."

The Amendment has adopted a broader standard than that of the Pharmaceutical Compulsory Licensing Measures for issuing compulsory licensing of pharmaceuticals for any public health purposes. That is, the compulsory licensing provided under the Amendment is no longer limited to just "for the treatment of contagious diseases" as under the Pharmaceutical Compulsory Licensing Measures. This theoretically opens up a broad range of pharmaceutical therapies to compulsory licensing.

In the event of a public health crisis, such as SARS or bird flu, the Chinese government is likely to grant a compulsory license to manufacture and export the required patented drugs. For other nonpublic health matters (e.g., green technology), however, it remains to be seen if the SIPO is equally willing to grant a compulsory license. Recently, Chinese courts reportedly have denied a request for injunction in a patent infringement case after the patentee prevailed. This could signal the beginning of court-mandated compulsory licenses in China.

In addition to health-related compulsory licensing, the Amendment also provides that the Chinese government may grant a compulsory license on a patent involving semiconductor technology if the license for exploitation is limited to use for the purposes of public interest.

The amended Patent Law is now inextricably intertwined with the Anti-Monopoly Law in China. For example, Article 55 of China's Anti-Monopoly Law provides that "[t]his Law is not applicable to conduct by business operators to exercise their legitimate intellectual property rights in accordance with intellectual property laws and relevant administrative regulations; however, this Law is applicable to the conduct of business operators to eliminate or restrict market competition by abusing intellectual property rights." This very general language appears to present a concept similar to patent misuse under

United States law, where, for example, a patent holder would not be permitted to seek to leverage its lawful monopoly IP rights to extend them beyond the proper scope of the patent. Article 48 of the amended Patent Law stipulates that compulsory licensing may be granted to remove or reduce the negative effects of competition due to monopoly acts caused by the patentee exploiting the patent. In other words, the issuance of a compulsory license is now a remedy for patent misuse. However, what constitutes patent misuse in China is yet to be defined. China may look to the United States and Europe for guidance when dealing with patent misuse.

## CODIFICATION OF PRIOR ART DEFENSE

China has a split patent litigation system, with infringement determined by the courts and invalidity challenges heard initially by SIPO's Patent Reexamination Board. Therefore, patent infringement and invalidation proceedings often run parallel to each other. If the infringement proceeding progresses more quickly than the parallel invalidation proceeding, this could be rather disadvantageous to defendants, especially when the only viable defense is practicing what is in the prior art. While Chinese courts can stay the infringement proceedings pending the results of invalidation proceedings, they are not required to do so. Stays in design patent suits or utility model patent suits are granted more often than not, but most invention patent infringement suits are not stayed.

The current Patent Law does not explicitly identify practicing prior art as a defense to a claim of patent infringement. In practice, however, Chinese courts have allowed the prior art defense. The Amendment now codifies such judicial practice.

While it is not clear from the Amendment whether an accused infringer must practice exactly what is in the prior art, Chinese courts are likely to follow the approach taken by the Chinese Supreme People's Court in a 2001 advisory opinion concerning such defense.<sup>1</sup> According to the Chinese Supreme People's Court, the prior art defense can be established by showing that the accused product or process is identical to or obvious in view of the prior art.

## REGULATORY EXEMPTION FOR INFRINGEMENT

In many countries, their patent law provides a research exemption or safe harbor exemption as an exception to the exclusive rights conferred by patents, which is especially relevant to drugs. According to this exemption, despite the patent rights, performing research and tests for regulatory approval, for instance, does not constitute infringement before the end of the patent term. In the United States, this exemption, known as the Hatch-Waxman exemption, is codified in 35 U.S.C. § 271(e)(1).

The Patent Law does not expressly exempt activities related to regulatory review from patent infringement. Such an exemption currently exists as a judicial interpretation of the broad experimental use exception provided in the Patent Law. A Beijing Intermediate People's Court also recognized such exemption in its noninfringement findings. The Amendment codifies the judicial interpretation and practice by stating that it is not an act of infringement if a patented drug or medical apparatus is manufactured, used, or imported solely for the purposes of obtaining and providing information for administrative approval.

While the Amendment formalizes the exemption for activities related to regulatory review (this is a so-called "naked" Bolar exemption), it does not provide any provision for patent linkage with marketing approval. In addition, China does not afford patent term extension or patent term restoration, to compensate for regulatory delays in obtaining State Food and Drug Administration approval of drugs. Although some form of patent linkage has already been prescribed in the Pharmaceutical Registration Regulation, and the Chinese FDA has a set of procedures for implementing such patent linkage, it is essentially a toothless linkage scheme. This is because under this scheme, it is not an act of infringement to seek marketing approval. As such, it is of limited value.

---

1. Chinese Supreme People's Court Reply Letter No. 32[2002] of February 2, 2001 (最高人民法院民事审判第三庭关于王川与合肥继初贸易有限责任公司等专利侵权纠纷案的函 [2000]知监字第32号函, 2001年2月2日).

## INTERNATIONAL PATENT EXHAUSTION

The current Patent Law in Article 63 provides for domestic patent exhaustion, which applies to a product sold by the patentee in China. However, the language of Article 63 is not clear with respect to the importation into China of a product sold by the patentee outside China. The Amendment clearly provides for both domestic and international exhaustion of patent rights. Under the Amendment, it is not patent infringement when “anyone uses, offers to sell, sells or *imports* a patented product or a product directly obtained from a patented process, which has been sold by the patentee or by an entity or individual authorized by the patentee.” The addition of “imports” makes it clear that the parallel importation of patented products is not considered patent infringement in China.

The language of the amended statute does not make a distinction between restricted sales and unrestricted sales. Therefore, it is not clear whether international patent exhaustion can be prevented by contractual restrictions on the products sold. Moreover, international exhaustion, contractual restrictions, and antitrust issues interact in complex ways, and companies need to carefully structure their relationships in different jurisdictions to best achieve their business and commercial goals.

## PRELIMINARY INJUNCTION PROCEDURES

Article 61 of the current Patent Law authorizes courts to issue injunctions *before* filing an infringement suit, which may be translated as China’s efforts to implement its obligations to provide preliminary injunctive relief in patent infringement cases. In China, this is referred to as “pre-suit injunction.” The Judicial Interpretations on Application of Laws in Trials of Patent Related Lawsuits issued in 2001 by the Chinese Supreme People’s Court provides some procedural guidelines. Upon receiving a request for a preliminary injunction, a court must make a ruling within 48 hours if it finds that all procedural requirements have been properly met. The 48-hour time limit can be extended in special circumstances. Once issued, the injunction is immediately enforceable. The patentee, if it has not done so already, must then initiate an infringement action in the courts within 15 days of issuance

of the injunction, or the injunction will be lifted automatically. Either party may request the issuing court to reconsider its decision, which is an administrative procedure within the court. However, the injunction will remain enforceable during reconsideration and any subsequent proceedings until final judgment.

The Amendment incorporates the above procedures and further clarifies that the posting of a bond for a preliminary injunction motion is required. If no bond is posted, the motion will be denied. Moreover, the petitioner (*i.e.*, the movant) is responsible for any loss sustained by the respondent if the petitioner makes a mistake in the motion for preliminary injunction.

Notwithstanding the codification of preliminary injunction, obtaining a preliminary injunction in most patent infringement cases in China has always been and is becoming increasingly more difficult. Both infringement and irreparable harm must be clearly proven—a burden that is not easy to meet in China given the stringent evidentiary requirements and the lack of discovery procedures. Moreover, the Supreme People’s Court a few years ago tempered any early enthusiasm for the issuance of such injunctions by issuing an instruction to the lower courts urging caution in issuing preliminary injunctions and noting that preliminary injunctions should not be issued in cases involving nonliteral infringement or complicated technologies. Statistically, most plaintiffs in patent infringement cases do not seek a preliminary injunction for these reasons. For those who do request a preliminary injunction, the success rate is relatively high (*i.e.*, greater than 50 percent). It is yet to be seen if the statistics will change after the effective date of the Amendment.

## CODIFICATION OF EVIDENCE PRESERVATION

Article 74 of the Chinese Civil Procedure Law provides for “evidence preservation.” Where there is a likelihood that evidence may be destroyed or lost or difficult to obtain later, a party may seek an *ex parte* court order to seize such evidence before initiating a suit. The court may demand that the requesting party post a bond. An evidence preservation order is typically enforced by the judges themselves. Such

orders can be very effective, as the respondent generally will not be notified in advance and may be required to comply by providing the relevant documentation and evidence on the spot. In the execution of the order, the court may question the respondent, order production of documents, take samples of the infringing product, as well as conduct an inspection of the premises. Any evidence obtained from evidence preservation efforts is admissible in the subsequent court proceeding. Therefore, evidence preservation has become a powerful tool in patent litigation in Chinese courts. To prevent its abuse, however, most courts will require that the movant present some preliminary evidence showing ongoing or imminent infringement before issuing such an order.

The Amendment incorporates the above procedures into the amended Patent Law. Similar to the preliminary injunction procedures, a court should normally decide a motion for evidence preservation within 48 hours of receiving the motion. Once granted, the evidence preservation order must be executed immediately. The movant, on the other hand, must file a patent infringement suit within 15 days of the grant of the order. Otherwise, the court may nullify this procedural remedy, presumably by returning the obtained evidence to its owner.

## INCREASED STATUTORY DAMAGES

Under the current Patent Law, infringement damages are assessed on the basis of the following factors, in descending order of importance: (1) the actual loss suffered by the patentee; (2) the profits made by the infringer due to infringement; and (3) a multiple of the reasonable royalty found by the court. Where there is insufficient evidence of the patentee's loss, infringer's profits, or reasonable royalty, Chinese courts often award total damages of up to RMB 500,000 (about US\$72,500). Such damages award is prescribed in a Supreme People's Court judicial interpretation (which carries legal force in China). The Amendment codifies the award of statutory damages and also increases the upper limit to RMB 1,000,000 (about \$145,000). Moreover, the Amendment provides for the award of reasonable expenses incurred by the patentee to stop infringement that has already been in existence in regulations. However, in the past, Chinese courts only allowed very low recovery of expenses, and the situation is not likely to change.

## CONCLUSION AND NEXT STEPS

As indicated, the Amendment will come into effect on October 1, 2009. SIPO is currently working with the State Council Legislative Affairs Office to draft Implementing Regulations to the amended Patent Law, which are expected to also come into effect on October 1, 2009. Other rules, such as examination guidelines and revised rules regarding compulsory licensing, are being drafted to further implement the changes mandated by the Patent Law. At the same time, it can be expected that corresponding changes will be made in the existing judicial practice regarding patents, including changes to judicial interpretations and other guidance regarding patent infringement lawsuits. Importantly, the amended Patent Law left out two important issues. First, the doctrine of equivalents, which was in an earlier draft of the Patent Law, was not ultimately adopted into law. Chinese drafters and jurists noted that the doctrine of equivalents is largely a judge-made doctrine, and they therefore deemed it unnecessary to enact it into statutory law. Second, China had also contemplated legislating two other judicial doctrines: estoppel and laches, into the Patent Law. As China's statute of limitations for patent litigation is two years, the further addition of concepts of laches or estoppel could have further eroded a patentee's ability to seek full compensation for infringement. Moreover, it appears that consideration of such doctrines may need to await further revisions of other laws, as they could potentially affect other forms of civil litigation by their introduction into Chinese litigation practice.

The Third Amendment to the Patent Law contains sea changes that will significantly affect how Chinese and multinational companies will compete on the basis of patents in this emerging market. China is expected to generate more patentable inventions, and more patent applications will be filed and granted in China on behalf of applicants from overseas. The new law may change the way the patent game is played in China. First, patent invalidation will become more complicated because foreign evidence of prior public use, dissemination, and knowledge will constitute prior art under the new law. Second, patent litigation will also become more complex since the new law will allow the prior art defense and international patent exhaustion. Therefore, more

skilled patent litigators are needed to navigate through this uncharted water. Third, multinational companies will have to develop a proactive yet practical strategy for dealing with the possibility of compulsory licensing of patents in China. Finally, for those companies with R&D centers in China, there must be a patenting strategy that works for China, as well as the rest of the world.

As noted, the language of the Amendment is far from clear, so ambiguities still abound. Many of the ambiguities remain to be clarified in new regulations, rules, or judicial interpretations. Stay tuned for updates in the near future.

## LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our “Contact Us” form, which can be found at [www.jonesday.com](http://www.jonesday.com).

**J. Benjamin Bai**

1.832.239.3816 /

86.21.2201.8007

[bbai@jonesday.com](mailto:bbai@jonesday.com)

**Tony Chen**

86.21.2201.8079

[tonychen@jonesday.com](mailto:tonychen@jonesday.com)

**Mark A. Cohen**

86.10.5866.1103

[markcohen@jonesday.com](mailto:markcohen@jonesday.com)

**Chiang Ling Li**

852.3189.7338

[chianglingli@jonesday.com](mailto:chianglingli@jonesday.com)

**Ann W. Chen**

86.21.2201.8136

[awchen@jonesday.com](mailto:awchen@jonesday.com)

Jones Day publications should not be construed as legal advice on any specific facts or circumstances. The contents are intended for general information purposes only and may not be quoted or referred to in any other publication or proceeding without the prior written consent of the Firm, to be given or withheld at our discretion. To request reprint permission for any of our publications, please use our “Contact Us” form, which can be found on our web site at [www.jonesday.com](http://www.jonesday.com). The mailing of this publication is not intended to create, and receipt of it does not constitute, an attorney-client relationship. The views set forth herein are the personal views of the authors and do not necessarily reflect those of the Firm.