AUGUST 2008

WHAT DOES THE THIRD AMENDMENT TO CHINA'S PATENT LAW MEAN TO PHARMACEUTICAL COMPANIES?

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

A third amendment to the Patent Law is widely expected to be approved by the People's Congress soon. The latest draft of the third amendment was released for public comment on March 5, 2008 (the "Draft"). This *Commentary* discusses several changes to the Patent Law in the proposed third amendment and their potential impact on pharmaceutical patent protection in China.

TOUGH DISCLOSURE RULES FOR INVENTIONS RELYING ON "GENETIC RESOURCES" OR "TRADITIONAL KNOWLEDGE"

China is rich in genetic resources and traditional knowledge, and the Chinese government supports and encourages research to develop intellectual property derived from these assets. For inventions "completely relying" on genetic resources or traditional knowledge, the Draft for the first time imposes a requirement that the patent applicant disclose in the application the direct and original sources of the genetic resources or the source of the traditional knowledge.

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.

The Draft also stipulates that no patent shall be granted to inventions "completely relying" on genetic resources or traditional knowledge if the acquisition or use of the underlying genetic resources or traditional knowledge violated Chinese law or regulation.

Because of the stiff penalty attached to noncompliance with the requirements in the Draft, the international business community has raised concerns with the Chinese government about the potential chilling effect of the new rules on commercial research and development related to "genetic resources" and "traditional knowledge."

ABSOLUTE NOVELTY REQUIREMENT FOR PATENTABILITY

Article 22.2 of China's existing Patent Law has a blended novelty standard for patentability—in assessing novelty of an invention, Chinese patent examiners consider publication anywhere in the world but not public use outside of China. This blended novelty standard occasionally allows "patent hijacking," *i.e.*, the patenting in China of another party's invention witnessed at a public event (such as a trade show) outside of China. The Draft replaces this blended novelty standard with an absolute one, and it requires patent examiners to consider public use evidence from both inside and outside China in examining patent applications. Adoption of an absolute novelty standard will have the effect of reducing patent hijacking. The Draft does not state whether this absolute novelty requirement would be made retroactive. If so, it would open up the prior art space significantly for challenging the validity of existing Chinese patents.

HEAVY PENALTY FOR FOREIGN FILING WITHOUT A LICENSE

As international pharmaceutical companies set up research and development centers in China, they need to consider where to first file patent applications for inventions made in China. Today, Article 20.1 of China's Patent Law requires that a Chinese patent applicant for an invention made 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 assign the right to apply for patent to an entity outside of China and circumvent the foreign filing requirement of the current Chinese patent law.

The Draft blocks this "loophole" with a foreign filing license regime like the system in the United States. Under the new requirement, for any invention made in China, the applicant must obtain permission from the State Intellectual Property Office prior to filing a patent application in a foreign country. In most cases, the foreign filing license automatically will be granted shortly after the filing of a Chinese patent application. Violation of this requirement will result in loss of patent rights in China.

Because Chinese patent applications must be submitted in Chinese, this new rule will force international pharmaceutical companies to develop resources to draft original patent applications in Chinese to protect inventions made in China.

STRENGTHENING PATENT CO-OWNERSHIP RIGHTS

As pharmaceutical 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 Draft includes provisions that prevent unilateral use of the patent rights without the consent of co-owners.

Specifically, the Draft states that unless agreed upon otherwise, consent by all co-owners is required for (1) assigning the right to apply for a patent; (2) assigning or withdrawing the patent application; (3) assigning, abandoning, or pledging the patent right; and (4) licensing others to exploit the patent. Under such rules, pharmaceutical 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 co-owner.

ROAD MAP FOR COMPULSORY LICENSES

No compulsory license has ever been granted in China even though Chapter VI of China's current Patent Law contains compulsory license provisions. However, the Draft contains new rules that will make it more feasible and likely for compulsory licenses to be granted in China.

First, the Draft provides that the government may grant a compulsory license to a party qualified to exploit the patent if the patent owner, without justification, has not exploited or sufficiently exploited the patent three years after the patent grant. The Draft also provides that a compulsory license may be granted if it is judicially or administratively determined that the patent owner used the patent right in an anticompetitive fashion.

In addition, the Draft authorizes the grant of a compulsory license "where the public interest so requires" and where a developing country with no or insufficient capacity to manufacture a patented drug for treating an epidemic disease "hopes to import the drug from China."

International pharmaceutical companies have voiced serious concerns about the breadth and ambiguity of the compulsory license provisions in the Draft. The shaping of these provisions in the final stages of the lawmaking process deserves careful monitoring by the pharmaceutical research community.

FORMALIZATION OF THE REGULATORY REVIEW EXEMPTION

China's 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 Chinese patent law. The Draft codifies the judicial interpretation by stating that it is not an act of infringement if a patented drug or patented medical apparatus is manufactured, used, or imported solely for the purposes of obtaining and providing information for administrative approval.

While the Draft formalizes the exemption for activities related to regulatory review, it does not provide any provision for patent term extension to compensate for regulatory delays in obtaining State Food and Drug Administration approval of drugs. Neither does the Draft provide a patent linkage system like the Hatch-Waxman patent certification and 30-month stay mechanism.

CONCLUSION

Strong patent protection in China for pharmaceutical inventions is a top priority for the international pharmaceutical industry as China's pharmaceutical market grows by leaps and bounds and China becomes a center of pharmaceutical research and development. The proposed amendment to China's Patent Law contains changes that will significantly affect how pharmaceutical companies will compete in this market. Recent examples in China show that the government will take note of comments from the international business community in making and amending laws. Pharmaceutical companies planning to be active in China should make their opinions heard.

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General e-mail messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Tony Chen
86.21.2201.8079/
1.858.314.1200
tonychen@jonesday.com

Ann W. Chen
86.21.2201.8136
awchen@jonesday.com