



## Legal Affairs

# Update on Patent Law Revisions in China

## New Amendments Predicted to Affect Intellectual Property Protection

Lisa A. Haile, J.D., Ph.D.

The new year will bring many changes and their associated risks and opportunities. With President-elect Barack Obama leading the U.S. through one of the murkiest financial times in history, many are looking toward China in the year of Yi Chou, or the Ox, as we contemplate alternative funding sources, manufacturing locations, and sites for performing clinical trials.

It appears that China is poised to become one of the new centers of innovation. China intends to soon grant more patents than any other country and expects to entice most of the top pharmaceutical companies to conduct R&D within its borders. It is believed that China's government may show more incentive to enforce patent rights within the country if the local companies in China feel that they have innovative technologies and are, therefore, stakeholders in the growing biotech industry.

China's patent laws were initially created in 1984, long after most other

countries worldwide. The patent laws have been revised two times since 1984, first in 1992 and again in 2000. A third proposed revision is expected to be finalized early in 2009 by the PRC State Intellectual Property Office (SIPO). Part of the intent behind the proposed amendments is to provide China with protection that will be both in line with national interests and supportive of domestic innovation.

In the past, investors have been reluctant to put their money in a country where patent protection and enforcement are unpredictable. Even though China has an obligation to protect intellectual property (IP) since joining the World Trade Organization in 2001, efforts toward IP protection have not been evident.

Several foreign business associations, especially from Europe and the U.S., have been closely monitoring the drafting process and actively lobbying for specific changes. There have been many concerns, especially over the requirement that an applicant disclose the source of genetic material as part of the patent application process and proposals for



Lisa A. Haile, J.D., Ph.D. ([lisa.haile@dlapiper.com](mailto:lisa.haile@dlapiper.com)), is a partner at DLA Piper and co-chair of the firm's global life sciences sector. Web: [www.dlapiper.com](http://www.dlapiper.com) Phone (858) 677-1400

substantive requirements not found in TRIPS, an international agreement administered by the World Trade Organization that sets down minimum standards for many forms of IP regulation.

With respect to enforcement, the proposed amendments include raising the penalty for patent infringement from 300% to 400% of illicit profits and increasing the damage payment from 50,000 yuan to 200,000 yuan, even if there is no profit from infringement. It is believed that such deterrents will change the perception that China is too lenient with respect to enforcement of IP rights, especially for foreign patentees.

Article 48 of the amendment allows the granting of a compulsory license when a patentee is determined to be abusing his IP rights in order to prevent or restrict competition. In addition, the draft amendment outlines several situations where a compulsory license for a patent may be granted by the SIPO—

Articles 49 and 50 allow for the granting of a compulsory license in order to treat or prevent an epidemic in China, or when a developing country needs to import a pharmaceutical product from China for the same purposes. In the U.S., a similar provision is called march-in-rights.

What is more disconcerting is the proposal to grant a compulsory license, upon request, for the use of a patented invention if the patent owner, “without any legitimate reason,” has not “adequately practiced the patented invention for three years after issuance of the patent...” This section of the compulsory license amendment may be especially prejudicial for the biotechnology industry.

Consider the typical situation where a technology is under development and a patent application is filed in the U.S., followed by a PCT (Patent Cooperation Treaty) application, and then later filed in China.

In many instances, the claims that are issued or granted in a patent (the patented invention) are not actually practiced at the time of the patent grant or even within three years of the patent grant. Should companies consider setting up a small clinical trial in China as soon as the Chinese patent is granted? Would that qualify as adequately practicing the claimed invention?

The ambiguity in the language of this proposed amendment, combined with the potential impact of patentees losing rights in China for inventive contributions as determined by the SIPO makes this section particularly disturbing for life sciences companies seeking patent protection in China.

### **Patent Infringement**

Article 74 proposes to add “parallel importation” as an exception to infringement. This amendment would clearly jeopardize the rights of patent holders in

China. For example, if a product patented in China is sold outside of China and then imported back into China by another party, the Chinese patent rights are deemed to be exhausted.

What would prevent individuals or companies from targeting particular Chinese patented products in a troll-like manner, waiting for them to be exported from China, and then immediately importing them back into China with no penalty? Where is the incentive for foreign businesses to patent and manufacture their product in China knowing that exportation of the product would likely lead to future patent exhaustion based on acts of others that are out of their control?

An additional amendment to Article 74 provides an exception to infringement similar to the U.S. Bolar exception. It would allow the use of a Chinese-patented invention without running the risk of an allegation of infringement, if the otherwise infringing use is shown to be “related to providing information required to obtain regulatory approval.”

Similar to the situation in the U.S., this would also allow a generic drug manufacturer to prepare for product launch once the brand-name drug patent expires. This amendment would certainly make it more attractive for generic drug companies to begin to set up manufacturing facilities in China.

### **Filing in China First**

The current patent law in China requires Chinese individuals and entities to first file applications in China for inventions made in China. The amendments propose to extend the requirement to non-Chinese individuals and companies or “any individual or organization” such that an inventor must file a patent application in China first if “an invention is made in China.”

The controversial aspect of this

amendment is that when a patent application is filed outside of China for any invention made first in China (including improvements of existing inventions) without permission from the Chinese patent administration, a patent application filed later in China based on the same subject matter and/or claiming priority to the foreign filed application, will be denied approval in China.

These proposals are found in amended Articles 4, 20, and 76. This new rule will prevent a foreign parent or partner company from having a choice as to where the patent application is to be filed first, regardless of the citizenship of the inventors.

How will this affect investors or potential partners doing deals in China for research and development? In the U.S., having a patent portfolio including at least one if not more filed patent applications in the United States Patent and Trademark Office is sometimes critical to tip the scales toward investment or a pass on an opportunity. Will investors and potential development partners be swayed by the existence of patent applications filed only in China where the patent laws and their application through the SIPO are much less predictable? This lack of clarity and fear of inability to obtain valuable patents in China could greatly affect the desire of companies to do business in the country.

As the laws and court system in China slowly develop and evolve, foreign companies should be diligent in weighing the risks and benefits of doing business in China. A combination of language and cultural differences initially make it more difficult for foreigners, especially since guanxi, which is the basic dynamic of personal and social relationships, ultimately prevails in doing business in China. **GEN**