

Protection of Pharmaceutical IP in China

Contributed by Arthur Mok, Y. Jenny Luo, and Sloan Pavsner, Shanghai Hogan & Hartson LLP

The center of the global pharmaceutical industry is shifting eastward. Lured by China's inexpensive, highly-skilled workforce and booming consumer market, multinational pharmaceutical companies are increasingly exporting their research and development activities to China. Despite burgeoning foreign investment in China's pharmaceutical sector, however, foreign invested companies account for less than thirty percent of sales.¹ In this highly fragmented market, domestic companies dominate. And as the Chinese pharmaceutical sector grows at double digit rates, many of these domestic companies are poised to become future leaders in the global industry.

Against this backdrop, the Chinese government has proclaimed its intention to foster innovation in the pharmaceutical sector. It has issued a series of rules and regulations regarding the ways in which domestic and foreign-invested pharmaceutical companies can protect their drugs from intellectual property infringement, including patent protection, administrative protection, observation period exclusivity, data exclusivity, copyright protection, trademark protection, and trade secret protection, each of which is discussed below. Other types of intellectual property rights (IPR) not addressed here include plant variety rights, geographical indication rights for drugs and medical materials, pharmaceutical companies' rights to their commercial and domain names, variety rights for traditional Chinese medicines (TCM), anti-unfair competition rights, and rights for scientific discoveries.

Patent protection

The first Patent Law of the PRC was enacted March 12, 1984.² Though this recognition of intellectual property marked significant progress over the Cultural Revolution, the first Patent Law only protected drug-making processes and did not extend to the drugs obtained from such processes. Moreover, such process patents were only valid for fifteen years from the filing date of the application.

The first Patent Law was amended twice to extend the scope of its protection. The first amendment, effective January 1, 1993, expanded patentable subject matter to include chemical inventions and extended the patent protection of processes to the

products directly obtained from such processes. It also extended the term of invention patents from fifteen to twenty years from the filing date. The second amendment, effective July 1, 2000, brought the Patent Law into compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

As amended, the Patent Law provides three types of patent protection: invention patents, design patents, and utility model patents. Invention patents have a term of 20 years, while design and utility model patents are valid for only 10 years. Protection for all three types of patents may be curtailed if the patentee fails to pay relevant fees or otherwise abandons its patent.³

Patentable subject matter includes chemicals, pharmaceuticals, biologics, medical devices, biotechnology inventions, and TCM. The diagnosis and treatment of diseases are generally not patentable, but patent protection is available for methods of measuring physiological parameters for purposes other than diagnosis or treatment, as well as methods of processing data obtained from humans or animals. Patentable subject matter also includes drug packaging, as the colors, shapes and patterns of novel packages can be claimed in design patents.

With respect to patent priority, China follows the "first to file" rule, which means that the patent for a particular invention is granted to the first party to file a patent application, regardless of whether such party is the original inventor. Patents are filed with China's State Intellectual Property Office (SIPO) in Beijing, while SIPO offices at the provincial and municipal level handle administrative enforcement.

A third amendment to the Patent Law was recently approved by the National People's Congress Standing Committee and will become effective October 1, 2009.⁴ Consistent with international patent practice, the amendment adopts the "absolute novelty" standard, under which patent examiners must consider publicly known technologies and currently available designs both inside and outside China when processing patent applications. According to legal experts, the adoption of an absolute novelty standard may lead to a reduction in patent infringements.

Under the current Patent Law, a domestic entity or individual that wants to patent an invention completed in China must file an application in China before it does so abroad. The third amendment lifts this requirement, but also provides that patent

¹ PricewaterhouseCoopers, "Gearing Up for a Global Gravity Shift," available at

<http://www.pwc.com/extweb/pwcpublications.nsf/docid/76DEF9E310AB1DCD802572DF002C5ECA>.

² See 中华人民共和国专利法 [Patent Law of the People's Republic of China] (prom. 12 Mar. 1984, eff. 1 Apr. 1985).

³ Gerald Hane, "Intellectual Property and Innovation in China," George Mason School of Law, Aug. 2008, available at http://www.law.gmu.edu/nctl/stpp/ip_innovation.html.

⁴ See 中华人民共和国专利法 (2009 修正) [Patent Law of the People's Republic of China (2009 Revision)] (amd. 27 Dec. 2008, eff. 1 Oct. 2009).

applicants who intend to file abroad before they file in China must first submit their inventions to SIPO for review to ensure that they do not reveal any state secrets. Failure to do so will result in a loss of patent rights in China.

The amendment also addresses jointly-owned patent rights. It stipulates that, unless otherwise agreed upon, a joint owner can individually exploit the patent, or grant a non-exclusive license to a third party to exploit the patent. Any resulting royalties, however, must be distributed among the joint owners. This clarification on jointly-owned patent rights may be of particular importance to pharmaceutical companies engaged in collaborative research and development activities in China.

In addition, the amendment states that no patents will be granted to inventions that rely on genetic resources where the acquisition or use of such resources violates Chinese laws or regulations. The amendment also requires that, for inventions that depend on genetic resources, applicants must disclose both the direct and the original source of the genetic resources.

The amendment also provides that if a patentee fails to sufficiently exploit its patent without justification in the three years following the patent's issuance, the government may grant a compulsory license to another entity or individual capable of exploiting the patent. In addition, the amendment states that a compulsory license may be granted if it is judicially determined that a patentee used its patent right for anti-competitive purposes, or if national emergency or public health so requires.⁵ Although the public record indicates that no compulsory licenses have been granted in China, this new amendment suggests that China's policy toward compulsory licenses may have shifted.

At the same time, however, the amendment includes more detailed and specific patent protection measures. If a party attempts to portray non-patented products or processes as patented, the amendment increases the penalty from 300% to 400% of the illegal profits and raises the damage payment from RMB 50,000 to RMB 200,000, even if there is no illegal profit.⁶ For patent infringement, the amendment provides that courts can order the infringer to pay RMB 10,000 to RMB 1,000,000 in compensation when the exact damage cannot be determined, doubling the upper limit of RMB 500,000 in the current Patent Law.⁷

Administrative protection

In negotiations with the US government on intellectual property for China's accession to the General Agreement on Tariffs and Trade, the Chinese government promised to grant special administrative protection to drugs that were excluded from patent protection before 1993. Specifically, the Regulations for the Administrative Protection of Pharmaceuticals, approved by the State Council and promulgated by the State Pharmaceutical Administration in 1992, apply to drugs that: (1) were not subject to protection by exclusive rights in accordance with the provisions of China's Patent Law prior to January 1, 1993; (2) are subject to an exclusive right to prohibit others from making, using or selling them in the country to which the applicant belongs; and (3) have not been marketed in China prior to the date the application for administrative protection was filed. Only entities and individuals from countries that have concluded a bilateral agreement on administrative protection for pharmaceuticals with China may apply for administrative protection.⁸

For drugs that are granted a Certificate of Administrative Protection, the valid term of protection is seven and a half years from the issuance of the Certificate. During this term, the health authorities may not permit others to manufacture or sell the drug without the authorization of the owner of the exclusive right to the drug. If the drug is manufactured or sold without permission, the owner may request that the competent authorities under the State Council stop the infringing act. The owner of the exclusive right may also seek compensation in court.

Observation period exclusivity

According to the Provisions for Drug Registration of the State Food and Drug Administration (SFDA), after a new drug is approved for marketing in China, the SFDA will impose an "observation period" to observe the safety and efficacy of the drug. During the observation period, the SFDA will not allow any other enterprise to manufacture, distribute, or import this drug, unless it received approval to begin clinical trials for the same drug before the observation period began. Observation period exclusivity is available for new drugs manufactured in China and lasts up to five years from the date the drug is approved for production.⁹

⁵ The public health provision is particularly significant given that more than 100 million Chinese are currently living with Hepatitis B (HBV). Lamivudine, the antiviral drug used to treat HBV, is under patent protection in China, and is too expensive for the vast majority of Chinese HBV carriers to afford. With the recent amendment to China's Patent Law, calls have intensified for the government to issue a compulsory license for the production of Lamivudine. See "Civil Resolution on Promoting the Implementation of the Compulsory License Provision in the Revised Patent Law," SEA-AIDS, 9 Mar. 2009, available at <http://eforums.healthdev.org/read/messages?id=24282>.

⁶ Tuo Yannan, "Amendment of Patent Law Quicken," China Daily, 8 Sep. 2008, available at http://www.chinadaily.com.cn/bizchina/2008-09/08/content_7008088.htm.

⁷ Ibid.

⁸ 药品行政保护条例 [Regulations on Administrative Protection for Pharmaceuticals], art. 3 (prom. 19 Dec. 1992, eff. 1 Jan. 1993).

⁹ 药品注册管理办法 [Provisions for Drug Registration], arts. 66, 71 (prom. 16 Jun. 2007, eff. 1 Oct. 2007).

However, if the manufacturer does not proceed with production of the new drug for which the observation period is set within two years from the date of the drug's approval, the SFDA may approve another drug manufacturer to produce the drug and thereby reset the drug's observation period. Upon the expiration of the observation period, any enterprise may apply to register a generic or imported version of the drug.¹⁰

Data exclusivity

In accordance with the provisions in Article 35 of the Regulations for Implementation of the Drug Administration Law, undisclosed and independently acquired data submitted to the SFDA for the approval of a drug containing a new chemical entity are protected against improper commercial use for six years following the drug's approval date. Within that time, the SFDA will reject any application that uses the drug's undisclosed data without permission from the original applicant who obtained the drug's approval, unless the data submitted were independently acquired by the subsequent applicant.¹¹

However, Article 35 also provides two circumstances under which the SFDA may disclose such data: (1) when it is in the public interest to do so; and (2) when steps have been taken to ensure that the data are protected against improper commercial use.¹²

Copyright protection

The Copyright Law of the PRC was enacted in 1990 and amended in 2001.¹³ Copyright protection extends to scientific works including medical papers, specialized publications, research reports, and public health materials and data. It also extends to computer software and databases used for medical purposes, as well as novel package inserts or other printed materials for drugs, biologics, medical equipment, healthcare products, and medical materials. However, the Copyright Law protects only the form of, and not the concept or technology behind, these works. The term of copyright protection is 50 years where the copyright belongs to a legal entity.

Trademark protection

Since its promulgation in 1982, the Trademark Law of the PRC has been amended twice, first in 1993 and again in 2001 when China joined the WTO. The current Trademark Law, effective October 27, 2001, allows for the registration of trademarks,

service marks, collective marks, and certification marks, as required by TRIPS. The term of trademark protection is ten years. Within six months before the expiration of trademark rights, a trademark owner may apply to extend its registration for another ten years.¹⁴

Like patents, China has a first-to-file system for trademarks that "requires no evidence of prior use or ownership, leaving registration of popular foreign marks open to third parties. However, the China Trademark Office has cancelled Chinese trademarks that were unfairly registered by local Chinese agents or customers of foreign companies."¹⁵

The Trademark Office, under the State Administration for Industry and Commerce (SAIC), maintains authority over trademark registration, official recognition of well-known marks, and enforcement of trademark protection.

Prior to September 15, 2002, certain medical and health-related products, including chemical raw materials, antibiotics, TCM, biochemical drugs, radioactive drugs, vaccines, and blood serum products, were required to bear a registered trademark. With the amendment of the Trademark Law and the Administrative Law on Drugs, as well as the promulgation of Implementing Regulations for the Trademark Law, the registration requirement for these products was lifted. Nonetheless, while trademark registration for medical and health-related products is now voluntary, if such products do bear a trademark, the trademark must be registered.

Trade secret protection

The 1993 Anti-Unfair Competition Law of the PRC (Competition Law) prohibits the disclosure of trade secrets.¹⁶ The Competition Law defines trade secrets as certain technological and operational information that is not known to the public, is of economic value to the owner, has a practical application, and which the owner has taken measures to keep secret. Technological and operational information includes designs, procedures, product formulae, manufacturing techniques and methods, management secrets, customer lists, production and sales strategies, and the like.¹⁷

In accordance with the Competition Law, the SAIC promulgated Certain Regulations on Prohibiting Infringement of Trade Secrets (Regulations) in 1995. Under the Regulations, infringing

¹⁰ Ibid, arts. 69, 71.

¹¹ 中华人民共和国药品管理法实施条例 [Regulations for the Implementation of the Drug Administration Law of the People's Republic of China], art. 35 (prom. 4 Aug. 2002, eff. 15 Sep. 2002).

¹² Ibid.

¹³ See 中华人民共和国著作权法 (2001 修正) [Copyright Law of the People's Republic of China (2001 Revision)] (amd. 27 Oct. 2001).

¹⁴ See 中华人民共和国商标法 (2001 修正) [Trademark Law of the People's Republic of China (2001 Revision)] (amd. 27 Oct. 2001).

¹⁵ Hane, *supra* note 2.

¹⁶ 中华人民共和国反不正当竞争法 [Anti-Unfair Competition Law of the People's Republic of China], art. 10 (prom. & eff. 2 Sep. 1993).

¹⁷ See 关于禁止侵犯商业秘密行为的若干规定 [Certain Regulations on Prohibiting the Infringement of Trade Secrets], art. 2 (prom. & eff. 23 Nov. 1995, amd. 3 Dec. 1998).

ing behaviors are handled by the administrative authorities for industry and commerce at or above the county level (AIC). A party whose trade secrets have been infringed may provide evidence to the AIC and request an investigation. If the AIC finds that infringement has occurred, it may, in accordance with Article 25 of the Competition Law, order the infringing party to cease its illegal acts, and impose a fine of RMB 10,000 to RMB 200,000. The AIC also may confiscate any illegal income, order the destruction of infringing products, revoke the infringing party's business license, and remove the machines used to produce counterfeit goods. If money damages are sought, the party seeking damages must bring a civil action against the infringer in Chinese courts. The Competition Law stipulates that a nexus must exist between the damages sought and the illegal profit gained from the sale of the infringing goods.

In December 2004, the Supreme People's Court (SPC) and Supreme People's Procuratorate issued a judicial interpretation on handling criminal cases of IPR infringement, under which defendants convicted of trade secret infringement may be imprisoned for up to three years if the loss caused is "serious", which is defined as more than RMB 500,000 for an individual and RMB 1,500,000 for an enterprise.¹⁸ If the loss caused is "exceptionally serious", defined as more than RMB 2,500,000 for an individual and RMB 7,500,000 for an enterprise, courts may impose prison sentences of three to seven years in addition to fines.¹⁹

In February 2007, the SPC issued the first interpretation of the Competition Law (Interpretation) since its effective date in 1993.²⁰ The Interpretation defines and clarifies several key concepts, including trade secrets, in the Competition Law. For example, the Interpretation expands on the Competition Law's provision that trade secrets cannot be known to the public. It does not attempt to enumerate types of information that are "not known to the public", but it explicitly excludes six categories of information from the scope of trade secret protection, including information that is general knowledge in the field, and information that can be obtained from other sources or without

significant cost. The Interpretation provides that trade secrets do not have to yield actual economic benefits to their owners as long as they have the potential to do so and requires that trade secret owners take steps to maintain their confidentiality, such as encryption, passwords or codes, or contractual protections.

Conclusion

In recent years, China has demonstrated its commitment to IPR through a series of rules and regulations that provide companies with the means to combat infringement. Perhaps the best evidence of this commitment is the recent amendment to China's Patent Law. Unlike the two amendments that came before it, the third amendment was not driven by external pressure or the need to comply with an international treaty. Rather, it stemmed from China's own intellectual property agenda, which reflects the realization that it needs a strong IPR regime to sustain its meteoric rise in the global economy.²¹

China's arsenal of intellectual property protection measures enabled pharmaceutical companies to step up their research and development efforts in China, and prompted a shift in the global pharmaceutical industry. Given this shift, and the growing importance of the Chinese pharmaceutical market, it is critical for pharmaceutical companies in China to understand the IPR environment and the protection measures at their disposal. Their ability to do so may very well determine their long-term success or failure.

For more information, contact:

Hogan & Hartson LLP

Park Place, 18th Floor
1601 Nanjing Road West
Shanghai 200040
Phone: (86) 21 61223800
Fax: (86) 21 61223899

¹⁸ Hane, *supra* note 2; see 关于办理侵犯知识产权刑事案件具体应用法律若干问题的解释 [Judicial Interpretation of Several Issues Concerning the Application of Law in Handling Criminal Cases Involving the Infringement of Intellectual Property Rights] (prom. 8 Dec. 2004, eff. 22 Dec. 2004).

¹⁹ *Ibid.*

²⁰ See 关于审理不正当竞争民事案件应用法律若干问题的解释 [Judicial Interpretation of Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Unfair Competition] (prom. 12 Jan. 2007, eff. 1 Feb. 2007).

²¹ Weining Yang and Andrew Y. Yen, "The Dragon Gets New IP Claws: The Latest Amendments to the Chinese Patent Law," Hogan & Hartson, at 4.