

Fostering a Favorable Intellectual Property Environment in Chinese Biotechnology Industry

Janet Xiao and Kun Wang



About the Authors: Dr. Janet (Jian) Xiao is an associate specializing in patent law in the Palo Alto office of Morrison & Foerster LLP. She primarily represents clients in the areas of biotechnology and pharmaceutical industry in their world-wide patent procurement, patent portfolio management, and strategic planning. Dr. Xiao received a B.S. from Nanjing University, a M.S. from Institute of Biophysics, the Chinese Academy of Sciences, and a Ph.D. from the University of California, Los Angeles. She received her J.D. from the University of California, Berkeley.

About the Authors: Dr. Kun Wang is an associate in the Patent Group of Morrison & Foerster's San Diego office. His practice focuses on patent prosecution, patent portfolio development, and preparation of opinions pertaining to biotechnological, biomedical and pharmaceutical technologies. Dr. Wang received his J.D. from Georgetown University in 2008. He was an exchange student at the L.L.M. program at Tsinghua University Law School. Dr. Wang received a Ph.D. in molecular cell biology from Washington University, and a B.S. in biochemistry from Nankai University.

Despite the global economic crisis, China holds the promise of being one of the leaders in the world and China strategy has increasingly become an intrinsic part of multinational companies' business strategies. The Chinese biotechnology industry, including biopharmaceutical, agricultural biotechnology, industrial biotechnology, and environmental biotechnology, is one of the key areas of China's competitiveness and is expected to account for about 7-8% of China's GDP by 2020.¹ China's biotechnology industry also offers tremendous potential for multinational companies because of its vast market place, low cost pool of resources, relaxed regulatory environment, and extensive research and development infrastructure.

Over the years, China has gradually transformed from a pure manufacture base, raw material provider, and outsourcing post to the core of innovative research and development. China's biotech expertise already stands out at the international level with strength in areas such as gene mapping and profiling, transgenic technology, gene therapy, and stem cell research. Many multinational biotechnology companies have established R&D centers in China. Recognizing the importance of biotechnology innovation, the Chinese government has been aggressively investing in biotechnology. Over the period of 2001-2005, the annual government investments increased significantly by 400% from USD 100 million in 2001 to USD 1.2 billion by 2005. This figure is expected to reach USD 8.8 billion in 2020 as the government intends to transform China into one of the leading biotechnology players in the world.²

While China is expected to be a key player at the forefront of the global biotechnology arena in the future, there remain significant concerns about the lack of intellectual property protection in China.³ In order to provide strong incentives for domestic innovation and attract foreign innovative technologies, it is critical for China to improve its intellectual property environment. This article discusses the role of intellectual property in the biotechnology industry, China's progress and efforts in strengthening intellectual property protections, and identifies (1) public awareness of intellectual property, (2) increased understanding of the strategic value of intellectual property and (3) an effective infrastructure for intellectual property commercialization as key factors for fostering a favorable intellectual property environment in the Chinese biotechnology industry.

Role of intellectual property in the biotechnology industry

Modern biotechnology is a science-intensive field. Intellectual property, particularly in the form of patents, plays important roles in biotechnology development. Intellectual property rights granted to inventors provide the inventors with a temporary market exclusivity to commercialize their research and findings, and an opportunity to benefit from their inventions. In return, the invention becomes publicly known and free for use after the expiration of the intellectual property rights. The invention can then be utilized and built upon by the general public to create new innovations.

Biotechnology requires long term investment and is highly risky. Without the guarantee of market exclusivity, investors would be unwilling to invest in the risky business. Early-stage biotechnology companies typically focus on a small niche in the technology and rely on intellectual property as their main valuable asset. Intellectual property is thus critical for early-stage biotechnology companies to secure funding and/or collaborators; the value of the company largely depends on the value of its intellectual property. As a biotechnology company grows, intellectual property provides guidance for investing on a particular endeavor and assurance that the investment will have a reasonable return due to competitive advantages offered by the intellectual property protection. Intellectual property is also extremely important for mature biotechnology companies, which rely heavily on intellectual property protection to block generic competitors from entering the market. Upon expiration of the intellectual property rights, on the other hand, the innovation becomes freely available to the public, fueling the development of generic products.

China's progress and effort in intellectual property protection

The China strategy has increasingly become an intrinsic part of multinational companies' intellectual property strategies. In 2007, the Chinese Patent Office (the State Intellectual Property Office or the SIPO) received a total of 694,153 patent applications, which represents a growth rate of 21.2 percent over the previous year. In 2008, China received 828,328 patent applications, representing another increase of 19.4 percent over the previous year.⁴ This ranks China among the top in the world with respect to patent application filings.

Domestic companies in China have been increasingly active in seeking intellectual property protection. Among the 828,328 patent applications filed in China in 2008,

86.6 percent were filed by domestic applicants, a steady increase from 82.1 percent in 2006 and 84.5 percent in 2007.⁵ In 2008, China filed 6,089 patent applications under the Patent Cooperation Treaty (PCT), increased by 11.9 percent compared with the previous year.⁶ China moved from the seventh largest in 2007 to the sixth in 2008 in terms of the number of international patent applications. Moreover, Chinese telecommunication company Huawei Technologies was the largest filer of PCT applications in the world in 2008.

The Chinese government has placed tremendous emphasis on strengthening intellectual property protection in China and is determined to transform the country from resource and labor-driven economy to innovation-driven economy. In the "Outline of National Intellectual Property Strategy" issued by the State Council of the People's Republic of China on June 5, 2008 ("the Outline"), China sets the strategic goal that, by 2020, it will become a country with a comparatively high-level creation, utilization, protection and administration of the intellectual property rights. Implementing this strategy, the National People's Congress approved a Third Amendment to the Chinese patent law on December 27, 2008. The Third Amendment includes significant changes to Chinese Patent Law, and was intended to bring the law in line with China's current drive to promote domestic innovation and its attempt to reduce reliance on foreign-controlled patents. On March 29, 2009, the People's Supreme Court published guidelines on the implementation of the Outline.⁷ The guidelines, entitled "Comments of the Supreme People's Court on Implementing the National Intellectual Property Rights Strategy," set out a series of goals, including promoting the guiding roles of Chinese courts on intellectual property cases, increasing efficiency and consistency of the intellectual property adjudication system, and enhancing sanctions against intellectual property infringers. The Comment calls the courts to use all means, including damage compensation, injunctive relief, mitigation, and seizing goods, to ensure that infringers are effectively deterred and the damaged parties are sufficiently compensated.

Key factors for fostering a favorable intellectual property environment

Although China's progress on the intellectual property front is phenomenal, the overall intellectual property environment in China needs significant improvement. One of the key factors for fostering a favorable intellectual property environment in China is public awareness of intellectual property. Although the number of domestic patent applications has significantly increased over the years, the average number of filings per person in China

still lags far behind other Asian countries. There also remain significant regional differences in patent filings, with the majority of patent applicants coming from Beijing, Shanghai, and Shenzhen. Among the 6,098 PCT applications filed by the Chinese applicants last year, roughly one third were filed by Huawei Technologies. More than 90% of the Chinese enterprises have not filed any patent applications, and do not consider intellectual property as part of their business strategy.

Great effort should be invested on promoting public awareness of intellectual property rights. Innovative companies should be more aggressive in filing patent applications and be more vigilant in protecting their own intellectual property. On the other hand, companies should learn to respect other people's intellectual property. When a company delves into a new product, a new improvement, or a new territory of technology, it should examine its technology closely to make sure it did not misappropriate other parties' trade secrets or infringe other parties' patents. By doing so, the company can avoid unnecessary investment of time and money and the cost of a lawsuit at a later stage.

Another factor that is important for fostering a favorable intellectual property environment in Chinese biotech industry is an increased understanding of the strategic value of intellectual property. Intellectual property, particularly in the field of biotechnology, is a forward-looking long term investment by nature. Frequently, the value of intellectual property does not become apparent until during the late stage of the product development, and the intellectual property rights become the most critical during the last few years of the patent term. A clear understanding of a company's intellectual property portfolio is critical to effective intellectual property protection, yet it is frequently overlooked by Chinese applicants.

Among all the patents granted to domestic applicants in 2008, only about 15% were invention patents, i.e., patents granted after extensive examination and having 20 years of patent protection.⁸ The majority of domestic patent filings were applications for utility model and design patents, both of which are granted without substantive examination and provide the patentee with 10 years of patent protection. While utility model and design patents can certainly be valuable intellectual property assets, the overwhelming tendency of domestic applicants to pursue utility model and design patents reflects the general focus of domestic applicants on the number of granted patents and the speed of getting a patent granted.

Importantly, in order for intellectual property to be

an effective tool to block competitors, the scope and strength of intellectual property is essential. A narrowly drafted and claimed patent may be easily designed around and thus ineffective against potential competitors. On the other hand, a patented claim that is so broad as to encompass prior art will easily be invalidated and frequently ignored by competitors. The risky and high stake nature of biotechnology investment makes it particularly important to emphasize the quality of the intellectual property protection. Focusing on the number of granted patents and the speed of getting a patent granted can be misleading, because a patent application not being carefully drafted to carve out prior art and maximize protection can be valueless.

A third important factor that is important for a favorable intellectual property environment is an effective infrastructure for the conversion of the intellectual property into commercial products. In China, many research activities are carried out by individual applicants and research institutes. However, development of innovative technologies requires vast investment which is difficult for individuals and research institutes to achieve. An analysis in the biotechnology literature and patents in the years of 1991-2002 revealed that the ratio of scientific publications published and patent applications filed by biotechnology professionals in China is about 70:1, suggesting a relatively low level of transformation from scientific research into patentable knowledge.⁹ Although the ratio may have improved over the years, it evidences a need for fully realizing the value of innovative technologies, for example by establishing a market-oriented infrastructure that facilitates conversation and collaboration between individual inventors or research institute and private enterprises.

Notably, the Outline of the National Intellectual Property Strategy has identified fostering a culture of intellectual property rights as one of the key focuses for the Chinese intellectual property strategy. The Outline also laid out several strategic measures for achieving this goal, including: 1) setting up a working mechanism for publicizing information about intellectual property in which the public widely participates and 2) formulating and implementing a general education plan on intellectual property in education institutions.¹⁰ Moreover, the Third Amendment of the Chinese patent law and the Comments recently published by the Supreme People's Court provide much needed directions to the Chinese courts on improving procurement and enforcement of intellectual property rights. Effective enforcement sends a strong message about the importance of intellectual property protection and the consequence of ignoring intellectual property rights. Rigorous examination and

invalidation processes will ensure the quality of patents and reinforce the concept that the value of intellectual property depends on the quality of the patent rather than the number of patents or the speed of obtaining the patents. With these efforts, it is foreseeable that a favorable intellectual property environment will soon be developed in China.

Conclusion

Intellectual property protection is vital to the continuing economic competitiveness and progress in the Chinese biotechnology industry. At a time of tremendous economic turmoil and uncertainty, it is more important than ever for China to nurture the precious growth cycle of intellectual property and biotechnology innovations. If China can increase public awareness of intellectual property, improve public understanding of the strategic value of intellectual property, and establish an effective infrastructure for commercializing intellectual property, China's evolution into an innovation-driven economy will be swift and certain. .

References

1. Teh, "China's Biotech Long March," available at http://clearstate.com/admin/data/China_Biotech_Industry.pdf.
2. Id.
3. Minshell, "Does Offshoring Put Patents in Jeopardy?" Genetic Engineering & Biotechnology News, Vol. 29, No. 4, 2009.
4. SIPO website, available at http://www.sipo.gov.cn/sipo_English/statistics.
5. Id.
6. www.chinaview.cn, "China Moves up in International Patent Application Rating", available at http://news.xinhuanet.com/english/2009-02/04/content_10764477.htm.
7. Comments of the Supreme People's Court on Implementing the National Intellectual Property Rights Strategy, Chinese version available at <http://www.court.gov.cn/news/bulletin/activity/200903300001.htm>.
8. SIPO website, available at http://www.sipo.gov.cn/sipo_English/statistics.
9. Quach et al., "Biotechnology Patenting Takes Off in Developing Countries," Int. J. Biotechnology, vol. 8, Nos. 1/2, 2006.
10. Outline of the Intellectual Property Strategy, available at http://www.sipo.gov.cn/sipo_English/news/iprspecial/200806/t20080621_407693.htm.



Pharmaron is premier R&D service providers for the pharmaceutical industry, helping clients advance their projects in a timely and cost effective manner. With a world-class team of over 500 scientists and highly experienced and accomplished management in the US and China, Pharmaron provides partners with optimal outsourcing solutions in the drug discovery area, including synthetic and high throughput library chemistry, medicinal chemistry, biology, DMPK, in vivo pharmacology, process development and large scale manufacturing. In addition to strong stand-alone services in each area, Pharmaron also offers integrated drug discovery and development services.

Chemistry Services	In vitro ADMET and in vivo PK in rodent
* Medicinal Chemistry	* <i>Physical chemical properties assess.</i>
* Focused Libraries	* <i>Metabolic stability</i>
* Customer Synthesis	* <i>Protein binding</i>
* Process development	* <i>Caco-2 / PAMPA / MDCK permeability</i>
* Scale-up Synthesis	* <i>CYP phenotyping</i>
* Process development/manufacture	* <i>In vivo PK in rat and mouse</i>
Biology Services	In vivo Pharmacology Services
* <i>Assay development</i>	* <i>Oncology animal models</i>
* <i>Compound handling</i>	* <i>CNS - pain model</i>

Katherine Lee, 6 Venture, Suite 250, Irvine, CA92618 ; Tel : 562-686-9786 ; Fax : 949-788-9204 ; klee@pharmaron.com