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Intellectual Property Protection in China: Does it Warrant Worry?

The recent rise in patent application filings reflects new confidence in the future of patent protection

Some companies in the biopharmaceutical industry have considered and discarded their China strategy because they fear that intellectual property in China is unprotectable. While this may have been true a few decades ago, the situation in China is rapidly evolving. Companies not keeping abreast of changing policies may miss a significant opportunity.

Many foreign companies have demonstrated growing confidence in the Chinese Intellectual Property Rights (IPR) systems, by filing patents in China. Large biopharmas are setting up R&D facilities in Shanghai and Beijing, including Novo Nordisk, Roche, Eli Lilly and Pfizer. The recent entry of China into the World Trade Organization (WTO) and the rise of China's economy have pushed the protection and enforcement of IPR to the front burner for China's authorities, who plan to become major international technology trading partners.¹

Yet, despite these rapid changes and improvements in intellectual property rights (IPR), 80% of US companies recently surveyed by AMCham-China² have indicated China's IPR protection is "less than effective." Michael Wise of Perkins Coie outlines the background of IPR protection in China in his chapter in *Advances in Biopharmaceutical Technology in China*.¹

"China is on the verge of becoming a major technology and IP generator, creating a wave of patents likely to wash over the US and Europe's shores in the next decade, enabling China to dominate significant technology areas," says Ian Harvey, chairman of the Intellectual Property Institute in London. "This is the result of China's recognition of the fundamental importance of IP to economic growth." Harvey believes this shift has largely been missed by foreign observers.

BRIEF HISTORY OF INTELLECTUAL PROPERTY

According to Wise, intellectual property rights

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protection in modern China has had a history of little more than 25 years. Pharmaceutical's IPR history is even shorter. China's current legal IPR framework began in the 1980s; however, in that short time, China has made impressive strides in protecting and enforcing IPR. By comparison, the United States has had a tradition of protecting intellectual property rights for over 200 years.

IPR PROTECTION AND ENFORCEMENT IN CHINA

China joined the World Intellectual Property Organization in June 1980 and began to enact laws toward the building of a modern Chinese IPR protection and enforcement system. In the same year, the Chinese Patent Office was established. In 1998 the name was changed to State Intellectual Property Office. The patent law of the People's Republic of China (PRC) was adopted in 1984 and the copyright law was enacted in 1990. In 1993 the law of the PRC against unfair competition was enacted, which provided a statutory basis for the protection of trade secrets. Before these laws were enacted, IPR protection in China was minimal. Some scholars believe that legalized IPR protection started in China in 1882 when Emperor Guangxu of the Qing Dynasty granted the first "patent." It was only in 1992 that the PRC patent law was amended to extend patent protection to drugs.

ENFORCEMENT

Enforcement of IPR continues to be a major issue between China and the West today. China's central government is aware of the need to improve IPR protection and enforcement, but change cannot occur immediately in a country that has had such a limited history in IPR.

Enforcement of IPR in China may involve either the courts or the administrative authorities. Court actions take more time and money, but they can award damages, whereas administrative authorities can issue fines and award damages based on a successful mediation. While the number of cases filed in Chinese courts involving IPR disputes has increased rapidly in recent years, administrative actions remain the preferred venue in many cases. Patent disputes are handled by intellectual property offices. Trademark disputes are handled by the industrial and commercial bureaus. Copyright disputes are handled by copyright bureaus. Customs can investigate and seize imported infringing goods. Because IPR violations in China may also result in criminal penalties, police departments are actively involved in IPR related crimes.

PRC PATENT LAW BASICS

The 1984 PRC patent law took over five years to draft. The drafters examined the patent laws of the US, Europe, and other countries for reference. In many aspects, the PRC patent law is similar to European patent law. The PRC patent law is a first-to-file system that awards patents to the first applicant to file for patent, which differs from the United States, which is a first-to-invent system.

The 1984 PRC patent law was amended in 1992 to extend patent protection to drugs, which were previously excluded. Many block-

Figure 1. The number of patent applications received by the State Intellectual Property Office has increased at an annual rate of 20% from 1997 to 2005.¹

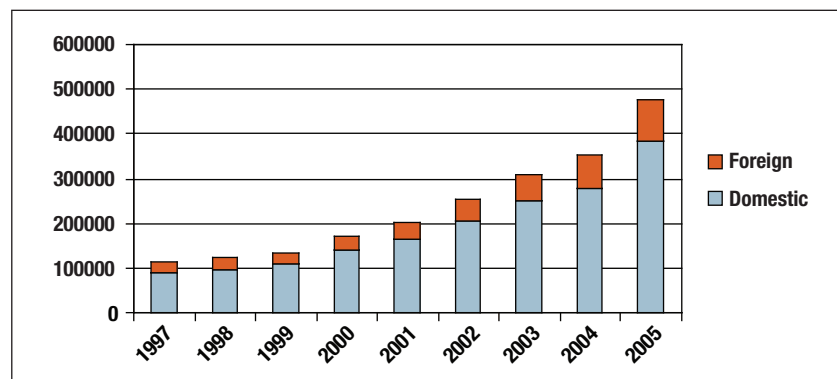
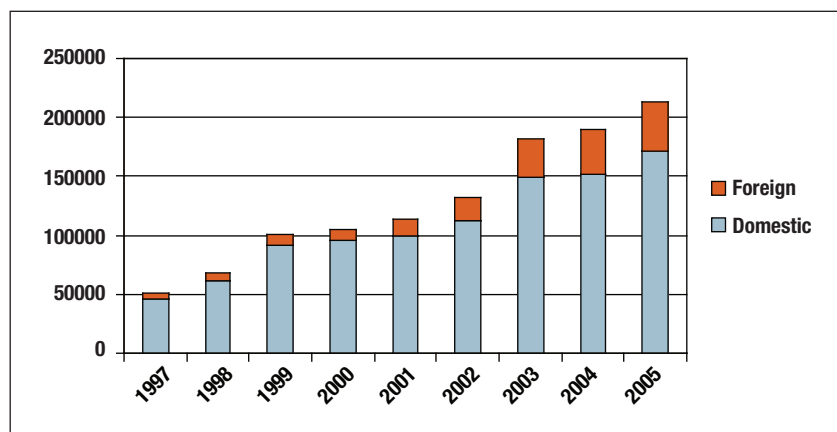


Figure 2. The number of patents granted by the State Intellectual Property Office between 1997 and 2005 has increased yearly.¹



buster pharmaceutical and biotech drugs that were discovered, patented, or publicly disclosed before 1984 were not eligible for patent protection in China. Consequently, companies in China produced generic versions of these blockbuster drugs before generic versions became available outside of China.

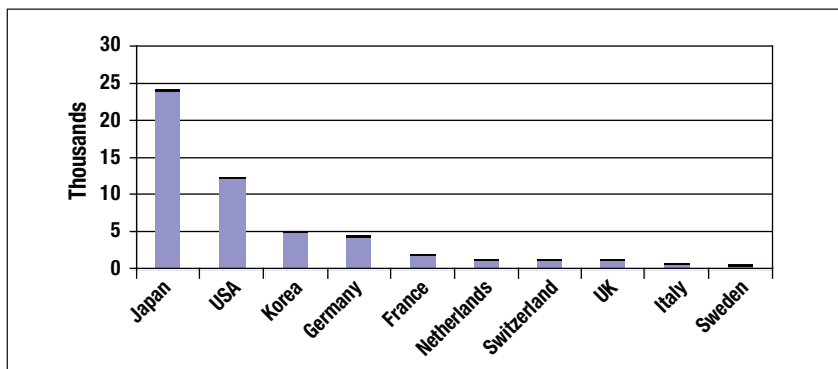
In 2000, amendments were adopted that further harmonized China's patent system with other countries in anticipation of China's joining the World Trade Organization. The implementation regulations of the PRC patent law were adopted in 2001 and amended in 2002. The PRC patent law provides that "no patent right shall be granted" for scientific dis-

coveries, rules and methods for mental activities..."

The PRC patent law also provides that creators of work-for-hire inventions should be compensated by their employers. "A state-owned enterprise or an institution" is required by law to pay an inventor no less than RMB2000 yuan (US\$250) for an invention patent.

RISING PATENT APPLICATIONS

The number of patent applications filed with the patent office by domestic and foreign applicants has risen rapidly in recent years. It took 15 years for China to reach its first one millionth filed patent application. However, it took only four years for China to reach its second millionth filed patent appli-

Figure 3. Top 10 foreign countries filing patent applications in China in 2003

cation. The number of patent applications has increased at an annual rate of 20% from 1997 to 2005 (Figure 1). Of the total of 2,761,189 patent applications filed from 1985 to 2005, 81.8% were filed by Chinese applicants and 18.2% by foreign applicants. In 2005, the number of patent applications by Chinese applicants increased by 37.4% over 2004. The increase in patent filings by Chinese applicants reflects a recent trend in IP awareness and focus by Chinese companies.

In 2005 alone, 214,003 patents were granted, of which 80% were granted to Chinese applicants and 20% to foreign applicants. On average, the number of patents granted by the patent office increased by about 20% per year between 1997 and 2005 (Figure 2).

In the medicine and pharmaceutical area, the annual percentage increase in patent application filings with the patent office has recently grown by double digits.³ The number of pharmaceutical patent applications filed for Western medicine was 3,263 in 2003, with an average annual growth rate of 27.4%. The recent growth in patent application filings reflects increasing confidence in the current patent system and the prospect of future patent protection and enforcement. It was not long ago that early-stage biotech and pharmaceutical companies would

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not consider China a country in which to file a patent application. Given the rapid expansion of the Chinese economy and the recent focus on IPR protection and enforcement, filing patent applications in China has become far more important than it was five years ago. China should be considered as a potential country in which to file patent applications for any international patent portfolio (Figure 3).

CHINA'S IPR ENFORCEMENT SYSTEMS

Chinese remedies for patent infringement are similar to US remedies. In a patent infringement case, the patentee may seek injunctive relief and monetary damages. However, unlike US plaintiffs,

Chinese plaintiffs often demand a public apology for the infringing activities. Patent infringement damages may be calculated as lost profits of the patent holder or benefits gained by the infringer. If royalty payment references are unavailable, a court may award damages from 5,000 yuan (US\$625) to 500,000 yuan (US\$62,500).⁴ Since the damages awarded for patent infringement in China are insignificant compared with the millions of dollars routinely awarded in US patent cases, the lack of meaningful damages for patent infringement is a significant issue between the United States and China.

Enforcing patent infringement judgments can be difficult in China due to local economic protectionism. If the defendant is a major employer of the region and produces significant tax revenues to the local government and the plaintiff has no operation in the city or province, the local government has no incentive to enforce the judgment against the defendant. If enforcement of the judgment would result in the closing of the business or severely curtail the success of the company, the local government may not cooperate in enforcing the judgment. This creates tension between the central government and the local government. The uncertainty in enforcement of judgments, in combination with the low damages available for relief, has discouraged many foreign companies from pursuing patent infringement actions in China. The lack of transparency in the Chinese court system and the interconnection of the parties further deter foreign companies from suing. Court decisions often are not published.

Through 2004,⁵ IP offices nationwide accepted 12,058 patent dispute cases, of which 10,411 cases (86.3%) were completed. In 2004 alone, the Chinese IP offices took

on 1,455 patent dispute cases and uncovered 3,965 fake patent cases.

CRIMINAL PENALTIES

IPR infringers in China may be subject to criminal penalties. From 1998 to 2004, 2,057 criminal cases were adjudicated in Chinese courts, and 2,375 individuals were convicted. According to the criminal law, "counterfeiting other people's patents" will, under "severe circumstances," result in either fines or up to three years of imprisonment or detention, or both. Criminal penalties for trade secret theft are punishable by either fines or up to three years of imprisonment or detention, or both. Trade secret theft causing damages of more than 2.5 million yuan (US\$312,500) to the holder of the trade secrets is punishable by three to seven years of imprisonment.

From 2000 to 2004, 2,533 suspects were arrested and 2,566 were charged by the prosecutors' offices for IPR crimes. In 2005, the police department investigated 1,799 cases and solved 1,470 cases (up 46% from 2004).

PFIZER'S RECENT CASE

Pfizer's Viagra patent case has received significant worldwide press. The patent claims the use of sildenafil citrate, the active ingredient of Viagra, for treatment of male erectile dysfunction. An invalidation proceeding joined by 12 domestic Chinese pharmaceutical companies was initiated in 2001. Nearly three years later, the reexamination board issued a decision declaring the patent invalid. Pfizer immediately appealed. In June 2006, the Beijing No. 1 Intermediate People's Court dismissed the reexamination board's invalidity decision and remanded the case to reevaluate the validity of the patent. An appeal was filed by the Chinese companies to reverse the decision. Without new

The Intellectual Property Institute's Ian Harvey outlines some of the shifts in China's IP landscape:

1. IP law in China is of a high quality by global standards.
2. Enforcement of patent rights is much cheaper and faster than in most developed countries.
3. In 2004 there was more patent litigation in China than in any other country, including the USA. 98% of cases were Chinese company vs. Chinese company.
4. At least 90% of the foreign companies litigating their patents in China win their cases vs. 30–40% of foreign companies litigating patents in the US.
5. China has only one third the number of patent examiners it needs. Newly trained examiners lack experience as do the majority of judges hearing IP cases. It will take 5–10 years to remedy this training and experience deficit.
6. China shows signs of regaining its historical creative and innovative position. Chinese universities now file as many patents in China as do the US universities in the US, and six times those of UK universities in the UK.
7. China currently files fewer than 2% of its internal patent applications outside China.
8. The leadership in China has a deep understanding of the role that IP plays. Prime Minister Wen Jiabao has said on many occasions that, "Competition in the future is competition in IP."

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evidence, it may be difficult for the Chinese companies to reverse the decision. The development of the Viagra case has been closely watched by Chinese and foreign companies as a test of China's IPR system. The Viagra case is an example of concerted efforts by Chinese companies to invalidate Chinese patents owned by a foreign pharmaceutical company. The fact that

Chinese companies are monitoring and opposing the grant of Chinese patents demonstrates an increased awareness of other companies' IPR and a sophisticated IP strategy. Rather than simply ignoring Pfizer's patent, the Chinese companies challenged it in court.

IPR CHANGES IN CHINA

For a country with only 25 years of IPR protection tradition, China has come a long way. China is preparing a third round of amendments to the PRC patent law (to be finalized by 2008).⁶ These amendments have resulted from China's entry into the World Trade Organization (WTO). The proposed changes indicate that China is continuing to strengthen and harmonize its legal system for IPR protection. The shifts will likely include: 1) changes in the patent application process; 2) amendments regarding legal requirements for patentability; 3) amendments regarding the exemptions to patent infringement; 4) amendments to establish a special appellate court to handle IPR cases.

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MANAGING IPR RISKS IN CHINA

IPR protection and enforcement are major issues for foreign companies contemplating doing business in China. The current IPR protection and enforcement in China are major issues in making decisions related to setting up operations in China that handle proprietary technology including R&D centers.

According to Perkins Coie's Michael Wise, foreign entities conducting business or considering doing business in China should incorporate IP risk management strategies as a component of their business plan. If a company is to establish an R&D facility in China, emphasis should be placed on managing the IP asset leakage and protection. To prevent this, precautions should be taken such as using experienced IP professionals in establishing the facility, creating confidentiality policies, and training employees. The majority of employees in China have not been exposed to confidentiality policies, so the company should educate and train all the employees about these policies.

An R&D company should aggressively seek patent protection for inventions made in the R&D facility in China. Despite the current limitations of IPR protection and enforcement in China, filing patent applications today may provide valuable IPR protection in years to come. Due to the brief history of patent protection in China and the differences between US patent law and the PRC patent law, many concepts are foreign to the Chinese,

including Chinese patent attorneys.

CONCLUSION

IPR protection in modern China has had a very brief history. Despite such a short timeframe, China has made impressive progress in protecting and enforcing IPR. China still has a long way to go. As the Chinese economy matures and China transitions from a manufacturing-based economy to a technology-based economy, IPR will become more important. The recent rise in patent application filings by domestic and foreign applicants bodes well for China and reflects an increased confidence in the future of patent protection and enforcement in China. The Chinese government is aware of the need to improve IPR protection and enforcement. The proposed third amendments to the PRC patent law will hopefully continue to improve the situation. The key question is when Chinese IPR protection and enforcement will meet international standards.

That timeframe may be shorter than some anticipate. Novartis is investing US\$100 million in its first comprehensive R&D center in Shanghai, Jeffrey Li, president of Novartis China, told reporters from China Pharmaceutical News, "Pharmaceutical R&D is...very sensitive to IPR issues. If a novel compound can get effective IP protection it may generate billion of dollars of profits...Novartis is fairly confident with China's IPR protection. We are voting [for

China's IPR protection] with billions of dollars." ♦

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