JONES DAY

APRIL 2006

HOW TO PROTECT PHARMACEUTICAL PRODUCTS IN CHINA WITH OR WITHOUT A PATENT

China surpassed the United States as the world's most litigious country for intellectual property disputes in 2005, with a total of 13,424 cases filed with Chinese courts. In comparison, 10,905 cases were filed in the U.S. during the same period.[1]

International companies were involved in only 268 of the IP cases filed in China last year, which represents an increase of 76 percent over the number in 2004. This overly cautious approach in IP enforcement by international companies in China is partly due to their unfamiliarity with Chinese civil litigation.

In addition, a significant number of international companies have opted not to apply for patents in China. For example, while companies from the U.S. have consistently filed more international patent applications under the Patent Cooperation Treaty than companies from other countries, they have been filing only half as many patent applications in China as their Japanese counterparts. One consequence of this inaction on the part of international life sciences companies is that many of their pharmaceutical products are not protected by patents in China.

This *Commentary* discusses practical approaches to three intellectual property issues frequently faced by international pharmaceutical companies in China:

- How to protect pharmaceutical products without a patent in China.
- How to deal with patent invalidation actions in China.
- How to enforce pharmaceutical patents in China.

1. These statistics come from the Supreme People's Court of China. A breakdown of the IP cases filed in China in 2005 is as follows: 6,096 copyright cases (vs. 4,595 in the U.S.), 2,947 patent cases (vs. 2,812 in the U.S.), 1,782 trademark cases (vs. 3,498 in the U.S.), 1,303 unfair-competition cases, 636 technology contract disputes, 156 plat varieties cases, and 504 other cases.

HOW TO PROTECT PHARMACEUTICAL PRODUCTS WITHOUT A PATENT IN CHINA

Patent protection has been available to pharmaceutical compounds, compositions, formulations, and indications in China since 1993. In addition, pharmaceutical products can be protected by the following regulatory mechanisms:

Monitoring Period Exclusivity. After a new drug is approved for entering the market in China, the State Food and Drug Administration ("SFDA") will impose a "monitoring period" to observe the safety and efficacy of the drug. During the monitoring period, the SFDA will not grant approval to any other enterprises to manufacture, distribute, or import this drug, unless the competing product has been approved for entering clinical trials in China prior to the beginning of the monitoring period. The monitoring period exclusivity is available for new drugs manufactured in China.

The monitoring period lasts from three to five years, starting on the issuance date of the drug manufacturing certificate.

Data Exclusivity. Under China's Regulations on Drug Registration, data submitted to the SFDA for the approval of a drug containing a new chemical entity is protected against improper commercial use for six years from the date of marketing approval. Such data exclusivity protection does not extend to new indications or formulations. A second applicant must generate its own data to support a competing drug registration.

Administrative Protection of Pharmaceuticals. Administrative protection of pharmaceuticals is a quasi patent protection designed to address the lack of patent protection in China for pharmaceuticals prior to 1993. Protection is available for active ingredients as well as dosage forms that meet the following requirements:

(1) No protection is afforded by the Chinese Patent Law prior to January 1, 1993.

(2) One or more patents were granted in the applicant's home country between January 1, 1986, and January 1, 1993.

(3) The item has not been marketed in China prior to the application date for administrative protection.

HOW TO DEAL WITH PATENT INVALIDATION ACTIONS IN CHINA

Patent Linkage. China's Regulations on Drug Registration require a drug manufacturer to declare that it does not infringe any third-party patent when filing a registration application. A generic drug manufacturer may file for registration with the SFDA two years prior to the expiration of a patent. The SFDA will review the application but withhold approval until patent expiration in China. In addition, a patentee may, on the basis of an infringement judgment, request the SFDA to revoke an approved drug registration.

Patent Invalidation Challenges. Because patent linkage provides an effective barrier to the introduction of generic drugs in China, there are an increasing number of invalidation proceedings at the Patent Reexamination Board ("PRB") of the State Intellectual Property Office ("SIPO") to challenge the validity of pharmaceutical patents. Patentees and invalidation petitioners have opportunities to file written comments and present oral testimony before the PRB. During the invalidation proceeding, the patentee can make amendments to the existing patent claims but cannot add claims or amend the specification of the patent. The decision of the PRB is subject to judicial review by the Beijing No. 1 Intermediate Court. Further appeal can be taken to the Beijing High Court.

In order to build a strong patent picket fence, pharmaceutical companies need to increase the number of their patent claims and enhance the quality of their patents in China. In addition, because a patent is considered valid in China until a final decision is made by the court,[2] pharmaceutical companies should use the appeal process in China to fully litigate the issues presented in invalidation proceedings.

2. For example, while the Viagra patent invalidation decision by the PRB is being appealed in China, the SFDA has not approved any generic copies.

HOW TO ENFORCE PHARMACEUTICAL PATENTS IN CHINA

International pharmaceutical companies have had litigation successes in China. For example, in 2003, GlaxoSmithKline stopped several generic drug makers from obtaining licenses for commercializing generic copies of Avandia, a patented drug for the treatment of Type 2 diabetes.

In China, as in other countries, litigation instituted by intellectual property owners is the main course for enforcement. The chief judge of the intellectual property chamber of the Supreme People's Court has encouraged international companies to bring more cases to court in China. In that regard, China has two routes for enforcing IP rights: administrative procedures and judicial actions.

Administrative Procedures. Depending on the nature of intellectual property rights and infringement, the IP owner can ask the State Administration for Industry and Commerce, the Public Security Department, the Copyright Office, the Trademark Office, or the SIPO to enforce intellectual property rights through inspection, seizure, reprimand, and fines. The administrative decisions in China are subject to judicial review.

In addition, upon identifying infringing products, the intellectual property owners can request Chinese customs to seize such products in an effort to prevent their export. To facilitate customs enforcement, the IP owner should record its copyrights, trademarks, and patents with the General Office of Chinese Customs.

Judicial Actions. China has a four-tier court system: the Supreme People's Court, the Higher People's Court, the Intermediate People's Court, and the Basic People's Court. The Supreme People's Court is the highest court in China. It handles appeals from lower courts and issues judicial interpretations and guidelines to clarify legislation or to harmonize lower-court procedures. Due to the complexity of patent cases, the Supreme People's Court has set up intellectual property chambers within the courts to hear patent cases; these chambers have the power to determine permanent injunction, preliminary injunction, and damages. At present, about 50 intermediate courts spread over the country have jurisdiction over first-instance patent-related civil disputes.

In China, there is no equivalent of discovery proceedings available in common-law jurisdictions. The general rule on presentation of evidence is that the party asserting the allegation bears the burden of proof. Therefore, the plaintiff in a patent infringement case is under the burden of proof and needs to collect sufficient evidence to discharge that burden. Moreover, any party may request the court for evidence preservation/collection under certain circumstances, such as when the evidence is likely to be lost or destroyed. There is an exception relating to patents covering the production process of a new product (*i.e.*, a product that was marketed in China before patent filing). In such cases, the alleged infringer must furnish proof to show that its production process is different from the patented process.

Upon winning a lawsuit, the IP owner is entitled to an injunction to deter infringement in China. In addition, the court has authority to order pretrial injunctions to stop infringement and collect infringement evidence.

Damages are determined as either the patentee's lost profit or the infringer's gain. Loss suffered by the patent owner is generally calculated by multiplying the patentee's loss in sales by the reasonable profit margin attributable to the product. Gain reaped by an infringer may be determined by multiplying the infringer's sales by a market average profit margin. If the patent owner's loss and the infringer's gain are difficult to calculate, royalties and patent license fee may be considered. Short of evidence for the above-listed calculations, the court may impose statutory damages. The court may also award to the patentee reasonable expenses incurred in halting the infringing act, including legal and investigation costs, although there are no punitive damages for patent infringement in China.

By proactively obtaining and enforcing patents in China, international pharmaceutical companies can play an important role in improving Chinese patent law and enforcement mechanisms.

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