

## SMART PILLS

### PROTECTING IP RIGHTS OVERSEAS

Local courts are just one tool in a box of remedies available to U.S. companies seeking to protect themselves in foreign locations.

—By Greg Mastel, James B. Altman, and Daniel P. Wendt

**P**fizer, Inc.'s recent trouble in China illustrates a growing problem. American companies are experiencing IP piracy more often and in more diverse locales. As Pfizer learned, respect for intellectual property varies beyond our shores, and local remedies in foreign countries may be slim or ineffective.

In 2001 Pfizer secured a Chinese patent for Viagra. But before that, the Chinese Ministry of Health had classified the drug as a controlled substance. That classification bans advertising and limits distribution by prescription to a small number of hospitals. This significantly handicapped Pfizer's marketing efforts. Meanwhile, Chinese generic drug makers were selling counterfeit Viagra, and challenging Pfizer's patent in the Chinese courts. In July the government overturned Pfizer's Viagra patent. The case is on appeal in China.

Encouraged by the Viagra victory, a number of Chinese companies are now attacking GlaxoSmithKline plc's Chinese patent for its diabetes drug, Avandia.

To protect their patents, Pfizer and Glaxo have more than the Chinese courts at their disposal. There are a number of remedies within the broader Greg Mastel is the chief international trade advisor and James B. Altman is a partner at Miller & Chevalier in Washington, D.C. Mastel most recently worked as the chief international trade advisor and chief economist for the Senate Finance Committee. Daniel P. Wendt is an associate at the firm.

field of U.S. trade and foreign policy. In some instances, these tools—informal and formal remedies—may be more effective than traditional legal tactics.

**To protect their patents in China, Pfizer and Glaxo have to look beyond the courts. Many times trade and foreign policy remedies have more bite.**

#### Formal Remedies

Section 301 Investigations: Either in response to a petition or on its own volition, the U.S. Trade Representative can initiate an investigation into a foreign unfair trade practice, including failure to protect intellectual property. Under this procedure, usually known as section 301 for its place in the Trade Act of 1974, the trade representative can negotiate to eliminate the practice, initiate a World Trade Organization complaint, and potentially retaliate against the foreign government involved.

The most likely basis for an IP-related section 301 petition is a World Trade Organization member's noncompliance with the agreement on Trade Related Aspects of Intellectual Property.

A section 301 investigation generally begins with consultations between the trade representative and the investigated country, which sometimes resolves the controversy. If consultations fail, the trade representative can file a complaint with the World Trade Organization,

which forms a dispute settlement panel to decide the merits of the complaint. The panel can authorize trade retaliation against the investigated country. If the country is not a trade organization member (such as Russia or Ukraine), the trade representative can impose trade sanctions on its own.

Special 301 Lists: The trade representative also defends IP rights abroad by preparing a Special 301 list, which identifies countries that do not adequately protect IP rights. The trade representative prepares the list after receiving comments from American companies. The most egregious IP violators are identified as "priority foreign countries," and are investigated by the trade representative.

Based on comments from the International Intellectual Property Alliance in 1998, the trade representative listed Paraguay as a priority foreign country and initiated an investigation. This pressure spurred Paraguay to sign a bilateral agreement on measures it should take to improve IP protection. Ultimately Paraguay was dropped from the list.

The trade representative won't always grant a company's request to put a country on the priority list. In those cases, countries can be placed on a Special 301 "watch list" or "priority watch list," which serves as a warning. The trade representative has included approximately 50 countries in the most recent watch lists.

Simply placing a country on the watch list can typically resolve an issue. For example, earlier this year, an

assistant trade representative testified to Congress that when Poland was added to the priority watch list, the Polish government almost immediately addressed the United States's concerns, including an effort to reduce counterfeit goods sold at Warsaw Stadium ["Property Line," May]. As a result, Poland was moved down to the watch list for 2004.

Generalized System of Preferences: The U.S. provides reduced tariff rates to developing countries provided they show a commitment to protect IP rights and promote other priorities of U.S. trade policy. An American company that is struggling to protect its IP in a developing country should check whether that country receives these kinds of benefits. For example, the International Intellectual Property Alliance petitioned to lift Pakistan's benefits, claiming that the country has allowed piracy to flourish, causing substantial trade losses. The trade representative recently accepted this petition and is now investigating Pakistan. The trade representative is similarly investigating Russia and Brazil.

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Section 332 of the Trade Act of 1974: American companies can draw attention to a country's failure to protect IP rights by encouraging the institution of a section 332 fact-finding investigation at the U.S. International Trade Commission. There are no enforcement provisions under section 332. However, the report can be a valuable reference for the administration and Congress

in their efforts to oppose a country's failure to protect IP rights.

#### **Informal Procedures**

Traditional Diplomacy: American companies can informally encourage traditional diplomacy. One purpose of the Bush administration's June delegation to China (weeks before the Viagra patent was invalidated) was to discuss IP protection. In China, U.S. secretary of Commerce Donald Evans emphasized that the country should curb rampant piracy and counterfeiting in its market. The delegation also included the acting Patent and Trademark Office director Jon Dudas and officials from PTO's Office of International Relations and Enforcement.

Sustained ambassadorial pressure in Greece played a key role in convincing the government to crack down on television stations showing movies without paying royalties.

U.S. officials frequently provide considerable technical and practical advice, too, including training programs, as well as substantive expertise.

Congressional Aid: American companies can encourage countries to protect IP rights by lobbying for a Congress member's support. Members of Congress can meet with foreign dignitaries, and convey that Congress will hesitate to grant benefits to a country that is not committed to protecting IP rights.

Trade Negotiations: When a foreign country is negotiating with the U.S. for a multilateral or bilateral trade agreement, American companies can work with the U.S. government to encourage that foreign country to improve IP protection. In particular, the trade representative has a private sector IP committee that often counsels the trade representative during negotiations.

Multilaterally, the trade representative can exert pressure on other trade organization members during negotiating rounds (such as the current Doha round) or in the trade organization's

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TRIPS Council. The council is specifically designed to foster ongoing negotiations and consultations pertaining the TRIPS Agreement and the protection of IP rights.

In the U.S.-Australian Free Trade Agreement the pharmaceutical industry used bilateral negotiations to add a provision to the agreement giving U.S. pharmaceutical companies greater opportunity to challenge Australian price controls on some drugs.

The protection of IP rights is similarly central to the ongoing free trade agreement negotiations between the U.S. and Thailand. The Intellectual Property Alliance recently asserted that Thailand had a 60 percent movie piracy rate and a 41 percent rate in records and music in 2003. Industry groups are urging the U.S. not to finalize any agreement until Thailand passes a licensing law that addresses the issue. At the least, the U.S. is expected to require Thailand to sign a side letter addressing these problems as a condition to any free trade agreement.

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