

WTO extends Article 31bis ratification

Poor countries seek access to cheap medications

Critics fear drugs won't get into hands of needy

# Patent Abuse

Drug companies lobby to stall WTO's new compulsory license provision. **BY STEVE SEIDENBERG**

**A lot of drug companies are getting increasingly nervous** about the ability of developing countries to override their patent rights in the interest of public health. In the past year, both Brazil and Thailand issued compulsory licenses for Efavirenz, a drug used to treat people infected with HIV/AIDS. Thailand overrode Merck & Co.'s patent on Efavirenz in December 2006. Brazil overrode it in May 2007. ¶ The countries acted under Article 31 of the WTO's IP treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

Article 31 allows countries to issue compulsory licenses under certain conditions, and critics say neither Thailand nor Brazil met them.

"What happened recently in Thailand and Brazil ... was an abuse of TRIPs," says Brad Huther, senior adviser for intellectual property at the U.S. Chamber of Commerce. He alleges the governments in those countries took the patents because they didn't want to pay royalties, preferring to spend government funds on other things.

But things might get a lot worse for the drug companies. Under proposed Article 31bis, the WTO would allow countries that can't make their own generic drugs to import them under a compulsory license.

Companies that develop new drugs are concerned about the proposed rule, claiming it will make it too easy for countries to essentially steal patents. Others criticize the provision as too harsh, imposing an expensive, cumbersome and time-consuming process on

poor countries. About the only thing the two sides agree on is that Article 31bis is turning into "a highly political issue," says Shamnad Basheer, who teaches international patent law at George Washington University Law School.

## Importing Drugs

WTO created Article 31bis to address a

problem with Article 31, which allows a country to issue a compulsory license that only covers drugs made—and predominantly used—within the country's borders. This is an insurmountable obstacle for many poor countries, which desperately need cheap medicines to combat epidemics such as HIV/AIDS, malaria and tuberculosis.

"The countries that most need these drugs lack the manufacturing capabilities to make the drugs," says John Iwanicki, a pharmaceutical patent attorney in the Boston office of Banner & Witcoff.

The WTO's member states attempted to solve this problem in 2003. They agreed that, under certain conditions, the WTO would waive the requirement that a compulsory license be limited to domestic use. A 2003 WTO Decision of the General Council sets out a detailed process whereby one country can issue a compulsory license to import drugs and a second country can issue a compulsory license to export the drugs



**A Brazilian customs worker unpacks a shipment of generic HIV medicine Efavirenz.**

to the needy country.

Two years later the WTO's members agreed to permanently add this waiver to TRIPs as Article 31bis. For the waiver to be included, 67 percent of WTO's members had to ratify it. But by the December 2007 deadline, only 13 of 151 WTO countries—about 8.6 percent—had ratified it. But Article 31bis isn't dead yet. The WTO pushed back the ratification deadline to December 2009. Meanwhile, the 2003 waiver remains in effect.

### Stealing Patents

The drug companies are one reason why so few countries have ratified Article 31bis. "They are lobbying a lot," says Elizabeth Haanes, an international drug patent attorney at Sterne, Kessler, Goldstein & Fox in Washington, D.C.

The companies are worried that the countries will divert drugs from the poor people who need them and resell them in more developed countries, thus harming patentees' full-price sales in those markets. Companies are also concerned that if drug prices are slashed in foreign countries this will generate political pressure in the U.S. to cut prices here, too.

As a result, many less-developed countries have been hesitant to ratify Article 31bis. "Smaller countries ... don't

want to make an enemy of the drug companies," Haanes says.

Many who favor compulsory licenses also criticize Article 31bis. They complain that this provision and the 2003 waiver don't go far enough and that the WTO-sanctioned process for getting drugs is too complicated, time-con-

suming and expensive (see "Licensing Hurdles").

They may have a point. In the four and a half years since the WTO enacted the 2003 waiver, only one country has used it—Rwanda in July 2007. Still, the mere threat of compulsory licenses is having an effect. "[I]t has allowed developing countries to negotiate better deals with drug companies," Haanes says.

### Lower Prices

Other experts predict that it is only a matter of time before politicians in small countries start recognizing the domestic political, social and economic benefits of importing cheap drugs. Moreover, as countries gain experience using the compulsory license procedures of the 2003

waiver, they will find ways to speed up the process and make it less expensive. This may force drug companies to either cut prices in certain foreign markets or accept the low royalties that come from compulsory licenses. Most drug companies, however, aren't so much concerned about losing revenue in these small mar-

## The companies are worried countries will divert drugs from the poor who need them.

kets as they are about the diversion of low-price drugs into more lucrative markets.

The lower prices should not have a major impact on the companies' profits, according to some experts, because the countries seeking cut-rate prices have limited sales potential. "The markets [in countries such as Rwanda] are fairly small, and the financial incentives to sell in such markets are small," Basheer says.

Drugmakers are more concerned with stopping diversion of the low-price drugs to other markets, and this is a manageable problem, according to many experts. "[A]lternate packaging and markings or color on the tablets/capsules [should] ... prevent or minimize this [danger of reimportation]," says Jamison Lynch, a pharmaceutical patent attorney in Mayer Brown's Chicago office.

The biggest worry for drug companies, however, is that countries will abuse compulsory licenses, employing them in the absence of any public health crisis, simply because the government wants to pay less for drugs. "[I]f Article 31bis were to be abused like the current compulsory license provisions are abused, that adds to drug companies' costs and risks," Huther says. "I don't think anyone has any reservations about getting drugs to developing countries, but we don't want to see these rights abridged in a way that hurts patent owners." ■

## Licensing Hurdles

ISSUING A COMPULSORY LICENSE ISN'T EASY. UNLESS THERE IS A national emergency, a country must first request a license from the patentee. If the parties can't agree on licensing terms within a reasonable time, only then may a country seek a compulsory license. Drug companies often have taken advantage of this requirement by stretching out negotiations for years.

After negotiations collapse, a country still must go through significant administrative formalities before it can issue a compulsory license. And if the drugs are to be imported from another country, the exporting country must go through the same formalities to issue its own compulsory license.

"The regulatory hurdles, especially for developing countries, are very high," says Elizabeth Haanes, an international drug patent attorney at Sterne, Kessler, Goldstein & Fox in Washington, D.C. "It is an incredible amount of red tape for countries that don't have the economic basis for that."