Drug patents focus of high-stakes tug-of-war

By THERESA AGOVINO
Associated Press

NEW YORK — A little purple pill is the world's biggest selling prescription drug, generating $6.3 billion a year in sales. That works out to about $17 million a day, or more than $700,000 an hour.

So given the amount of money involved, it's not surprising to find 12 companies fighting over the right to make a generic equivalent of Prilosec, a heartburn and ulcer medication at the center of 10 patent infringement lawsuits filed by drug giant AstraZeneca PLC.

The pretrial hearing set to begin this month in federal court in New York is likely to spotlight a growing trend among pharmaceutical companies: suing generic drug companies for infringement and adding new patents on lucrative medicines to extend their exclusive control.

"Whenever a brand-name drug is supposed to come off-patent, there is a lawsuit. Then there is the mysterious appearance of all these new patents," said William Nixon, president and chief executive of the Generic Pharmaceutical Association.

"It is almost shameless. Pharma companies are inventing new ways to keep generics off the market, and people are suffering."

Prilosec's patent expiration is in dispute, with generic-drug makers arguing that its protection should end in October. AstraZeneca counters that its Prilosec patents are valid for years to come.

Elsewhere in the industry, dozens of patent infringement suits have been filed, and more are expected because the stakes are enormous.

According to a UBS Warburg report, more than $30 billion in brand sales — about a third of prescription medicines in the United States — were slated to go off-patent between 2000 and 2005. The report says new drugs under development are not sufficient to replace lost sales due to patent expiration.

"It has really reached a breaking point this year," said Mara Goldstein, executive director of CIBC World Markets. "The problem is the patent laws were designed in a vacuum. Companies can continue to list legitimate patents, but that doesn't necessarily mean those patents contribute to good public health."

Pharmaceutical companies are allowed to sue those believed to be infringing on their patents, and to file new patents for new discoveries. Patents are the pharmaceutical companies' lifeblood, so a strong defense of intellectual property is essential to further drug development.

Pharmaceutical companies are allowed to sue those believed to be infringing on their patents, and to file new patents for new discoveries. Patents are the pharmaceutical companies' lifeblood, so a strong defense of intellectual property is essential to further drug development, industry executives say.

"Patents are the basis for our business model. The generics are not investing anywhere near the amount we invest in research and development," said David Brennan, senior vice president of AstraZeneca's U.S. Consumer business. "It is important for us to challenge tests to our intellectual property."

It is also their fiduciary responsibility to their shareholders.

"(The pharmaceutical companies) may spend $2 million in legal fees, but get another $100 million in sales," said Goldstein. "It is a good investment."

For example, Bristol-Myers Squibb received a new patent on its anti-anxiety drug BuSpar the day before the patent was set to expire, so generic competition was blocked until a federal judge ruled that the new patent should not stop the sale of a generic version.

The case is on appeal, but in the time between the patent issuance and the ruling, Bristol-Myers rang up at least $160 million in additional sales.

■

It wasn't supposed to be like this.

In 1984, Congress passed what is commonly called the Hatch-Waxman Act to ease entry of generic drugs into the market.

The law allowed generic companies to experiment on branded drugs while patents were still in effect, but in return owners of patented drugs were given more time to sell their products without competition — three years on average. AstraZeneca re-

See Patents, D2

SOURCES: Food and Drug Administration; SectorUpdates.com

AP

Patents focus of high-stakes tug-of-war

Continued from Page D1

ceived a two-year extension on the basic Prilosec patent.

Hatch-Waxman also created provisions for infringement lawsuits. Now, some insist pharmaceutical companies are exploiting loopholes in the law to sue generic companies.

At least two initiatives to tighten Hatch-Waxman are in the works.

Last Tuesday, Sens. Charles Schumer, D-N.Y., and John McCain, R-Ariz., introduced a bill aimed at getting generic drugs into pharmacies quicker.

The legislation would eliminate automatic stays granted to pharmaceutical companies who sue generics for patent infringement. It would also allow generic companies to directly approach judges to ask if their formulations infringe on patents.

Reps. Alan Mollohan, D-W. Va. and Ken Calvert, R-Calif., are also planning to introduce legislation in the coming weeks to address what they consider problems with Hatch-Waxman. They haven't released details of their bill.

And last month the Bush administration said it won't block a Federal Trade Commission study into whether major drug makers are routinely acting to delay competition from generic firms. The study began last month. Plus, various states are seeking ways to lower prescription drug costs.

All together, this adds up to tremendous government pressure on an industry that spends more on federal lobbying than any other.

Makers of branded pharmaceuticals devoted about $91 million to their information campaign in 1999, the last year for which statistics are available, according to the Center for Responsible Politics.

The battle over Prilosec illustrates what is at stake for pharmaceutical firms, generic manufacturers and consumers.

Prilosec is the crown jewel for London-based AstraZeneca, accounting for more than a third of the company's $18.1 billion in sales last year.

Earlier this year, AstraZeneca introduced Nexium, an improved version of Prilosec. This is a common strategy by drug companies to shift doctors and customers from one version of a company's drug to another while keeping generics at bay.

However, while Nexium proved better than Prilosec, some contended the difference wasn't that dramatic.

In fact, Nexium's price is lower than that of Prilosec, which is not common in the introduction of a new drug. Brennan insists the pricing reflects the market for ulcer and heartburn medications.

"It is traditional thinking to say if the drug represents a real advance, it gets a premium price, but there are a range of dynamics that go into pricing," said Brennan.

Still, both Ford Motor Co. and General Motors Corp. said they would encourage individuals in their health plans to use a generic version of Prilosec instead of Nexium.

Generic drugs are up to 50 percent cheaper than the patented product in the first year and 80 percent cheaper by the third year. That means a generic version of Prilosec could be around $2 per dose, while Nexium would cost $3.33.

GM believes savvy marketing was already pushing doctors to overprescribe Prilosec. The automaker spent $52 million on the drug last year, more than any other medication, says GM spokesman Rob Minton.

■

AstraZeneca has a compelling financial interest in making sure a generic version of Prilosec doesn't hit the market any time soon. A report by Goldman Sachs published in November 2000 says that AstraZeneca's earnings could be flat next year if Prilosec goes off-patent in October.

AstraZeneca insists its lawsuits are not a ploy to extend Prilosec's exclusivity. In fact, the company maintains it has legitimate patents on the drug until 2018.

"We believe these companies have infringed on our intellectual property, and it is our right to take action," said Brennan.

There are two facts that AstraZeneca and the defendants in the 10 lawsuits can agree on. The basic compound patent for Prilosec expired on April 5, and that with an extension for pediatric use, that patent would end on Oct. 5. That's when generic makers say they should be able to start selling their versions of the product.

AstraZeneca has five other patents on Prilosec, the last of which will expire in 2014, but generic manufacturers say their products wouldn't infringe on those patents. In the last few months, AstraZeneca had four new Prilosec patents approved as well.

"This is just ridiculous," said Elliot Hahn, president of Andrx Corp. in Davie, Fla., one of the companies being sued by AstraZeneca. "AstraZeneca just wants to delay us as long as possible."

Andrx, which is involved in a half-dozen similar suits involving other drugs, has spent $70 million on a new facility known as "Prilosec Park" to manufacture the generic version of the drug once the way is clear.

Bernhard Hampl, chief executive of Eon Labs in New York, has been trying to expand from generic versions of niche drugs to more lucrative blockbusters. As a consequence, the company is now a defendant in six lawsuits, including Prilosec, but he's sure everything will work out in the end.

"I'm convinced that public opinion is with us," said Hampl, "and the drug companies will have to leave this strategy."