



Court Deals Andrx a Blow

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Consumers received a big setback and investors pummeled shares of Davie-based Andrx Corp. on Monday after a federal judge ruled the company and two others infringed patents for the blockbuster drug Prilosec and are not allowed to market a generic version until those patents expire in 2007.

For consumers, the decision means they'll still pay about \$4 a pill for AstraZeneca LP's heartburn medication, unless they are covered by a drug plan in which their employer covers most of the cost of a prescription. Had Andrx entered the market, the price would have dropped to about \$3 a pill initially and then to perhaps less than \$2 as competitors emerged.

Many governors and members of Congress have blasted AstraZeneca's patent infringement claims, saying the American consumers, particularly seniors, were being victimized by a pharmaceutical company using ancillary patents to prolong its brand-name monopoly.

The coalition group, Stop Patient Abuse Now, which was founded by the Gray Panthers, has made Prilosec a key issue. The group's Web site has a display of how much it claims patients have overpaid for branded Prilosec versus the cost of a generic version. On Monday, that estimate had reached almost \$2.4 billion.

The mood at Andrx headquarters on Monday was of shock and disappointment. Analysts and industry observers had expected an Andrx victory, particularly in light of the company's strong track record in challenging patents of other major drugs and winning in court.

Employees and investors also faced a continuing drubbing from investment losses in company stock. Andrx shares closed Monday at \$12, down \$7.99, on volume of 19 million shares -- more than 12 times the average daily turnover. The stock traded as high as \$76.52 in December.

Newly named Chief Executive Officer Richard Lane said during a conference call with analysts Monday morning that he and other top management officials were keenly aware of the potential negative impact on 1,800 employees' morale and loyalty.

"It is important for the management team to meet with employees over the next few days and bring them the message we're bringing to you," Lane said. "We were never just a Prilosec company. It was an opportunity. It's not an opportunity we've given up on. It's certainly not the be-all and end-all of this company."

Andrx President Elliot Hahn said the company plans to appeal the ruling, adding he thinks the judge reached the wrong conclusion.

"We remain optimistic that an Andrx generic version of Prilosec will ultimately be marketed."

But the situation is more complex because Judge Barbara Jones of the U.S. District Court in Manhattan gave another firm, the KUDco unit of Schwarz Pharma AG the right to market a generic copy of Prilosec because its formulation did not infringe the patents.

The German firm has received tentative approval from the Food and Drug Administration, and it was unclear what route the company would take to get its version of a drug with \$5.7 billion in sales last year to the American consumer. A deal with Andrx, which might distribute KUDco's product in exchange for a share of the profits, seemed likely.

A deal might be the best and quickest way to get the product to market. That's because Andrx and

Merck KgaA's Genpharm Inc. have six-month exclusivity to market generic Prilosec -- the result of being the first to file with the FDA. That exclusivity remains in force until a final decision in the lawsuit, which could take a year or more because of the probable appeal.

Schwarz officials said they probably will talk to Andrx about obtaining its rights. Andrx is considering a deal, but would not comment on any possible negotiations. In addition to Andrx, Judge Jones ruled that Merck KgaA and India's Dr. Reddy's Laboratories Ltd. infringed AstraZeneca patents. The ruling sent AstraZeneca's shares soaring in London, up 13 percent. It was the company's biggest one-day gain in more than nine years.

The ruling shows the court did not react to "a push from Washington to get cheaper generic drugs on the market," said Jeffrey Kraws, co-president of The Investor Relations Group, an investment research firm. He said, though, this did not sour his high hopes for generic companies, particularly Miami-based Ivax Corp. Ivax, he said, has 34 applications pending at the FDA.

"It's a complete shock, and obviously it's anti-consumer," said David Saks, president of the \$20 million Saks Medscience Fund, which recently sold its Andrx shares. "I thought the odds were greater than 50 percent Andrx would win."

Andrx had thought the odds were pretty good, too.

The company had started production of its generic Prilosec so the drug could be shipped within days -- and possibly hours -- of winning in federal court. Now, Andrx might have to dump as much as \$30 million of the product and write off \$15 million in raw materials and \$20 million in purchase commitments.

Andrx, which had \$740 million in revenue last year, was expected to break even in the third quarter ending in September. It now plans to take an undetermined charge and probably post a loss.

CEO Lane said the Prilosec defeat would not create excess production capacity at the company's new plant near State Road 7 and Griffin Road. Rather, he said, other products already approved and in the pipeline could create a need for additional capacity elsewhere.