Debate follows unlikely ruling

Many see judge's AstraZeneca decision as a shift in the legal realm of drug patents

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10/20/2002

Soon after a federal judge upheld two key patents on AstraZeneca's top-selling heartburn medicine last week, the phone started ringing at J. Mark Pohl's house.

A former DuPont Co. researcher and biotechnology investment banker, Pohl is now a pharmaceutical patent lawyer in Morristown, N.J., who represents generic drug makers and small companies developing their own drug products. Clients wanted to know how the ruling on AstraZeneca's Prilosec drug would affect their products.

"I think almost every generic [company] would call the decision a surprise and a disaster," said Pohl, a University of Delaware graduate. "I had to hold everybody's hand."

But for brand name drug companies, which are known in the industry as pioneer or innovator drug makers, the 277-page opinion by U.S. District Judge Barbara S. Jones of the Southern District of New York, could signal a shift in the legal landscape. Historically, brand name manufacturers have tended to lose in their 18-year battle with generics.

The stakes are enormous. It now costs about $802 million to develop a new drug and only the few blockbusters produce enough revenues to match or exceed the average research and development cost, according to a June study by the Pharmaceutical Research and Manufacturers of America. Prilosec, a blockbuster product that has been called the best-selling and most profitable drug, had nearly $5 billion in sales worldwide in 2001. Sales of Prilosec represented more than a third of the entire company's revenues last year.

At the same time, consumers, insurers and employers are pushing for more access to cheaper generic products to lower health care costs that have been rising by as much as 14 percent annually. Pharmaceutical costs have been rising closer to 20 percent. For some companies, as much as 60 percent of health care costs for retirees older than 65 goes to pharmaceuticals. The average cost of a brand name prescription is $69, compared with $29 for a generic prescription, studies show.

Jones ruled that three generic drug makers - Andrx Pharmaceuticals Inc. of Davie, Fla., Cheminor Drugs Ltd. of Hyderabad, India, and Genpharm Inc. of Ontario, Canada - infringed on AstraZeneca's patents for how the purple pill is able to deliver omeprazole, the medicine that inhibits the secretion of stomach acid. This means that AstraZeneca's patent protections are valid through 2007, unless the decision is overturned in an appeal. The company's patent on omeprazole expired a year ago, but the formulation of the pill is covered by two patents.

"It's an important case for the pharmaceutical industry by supporting the proposition that valid patent rights enjoy protection under U.S. law," said Glenn M. Englemann, vice president, general counsel and secretary at AstraZeneca Pharmaceuticals in Fairfax.

Gwilym J. Attwell, a pharmaceutical patent attorney with Cozen O'Connor in Philadelphia, said the ruling seems all the more meaningful because so many people expected AstraZeneca to lose the case. Andrx built a $100 million production plant and was poised to begin selling a generic Prilosec if it won the case.

While the judge ruled that a fourth defendant - Kremers Urban Development Co. of Mequon, Wis. - had not infringed, Attwell said he believes AstraZeneca will most likely not face generic competition until its patents expire. For one thing, Andrx and Genpharm have been granted a 180-day period of market exclusivity by the Food and Drug Administration. This effectively keeps Kremers out of the market unless it strikes a deal with Andrx or Genpharm.

AstraZeneca has said it will appeal the Kremers portion of the decision.

Jones sits in one of five federal judicial districts in which most patent cases involving generic drugs are heard, according to a study done in July by the Federal Trade Commission. And the rate at which the Federal Circuit reverses decisions on patent validity and infringement has been just 8 percent of the cases studied by the FTC.

Regardless of the possible larger significance of this case, the ruling was a winning round for the brand name companies in their 18-year high stakes battle with generic competitors. The fight

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began when Congress passed what is commonly known as the Hatch-Waxman Act. That law created the generic drug industry by eliminating costly and lengthy clinical studies. Under the act, generics only had to prove their medicine is identical to that of the brand name manufacturer, something called bioequivalence.

Generic drugs now make up 47 percent of the prescriptions filled, compared with 19 percent in 1984, according to the FTC study.

Particularly worrisome to lawyers who represent the generics was Jones' eight-page discourse on how AstraZeneca researched and developed omeprazole and Prilosec over 35 years. Jones used phrases like "particularly difficult and challenging" to describe the work.

"She very sagely put in the human interest. This is a way people on an emotional level can see what the branded company went through to get this product," Pohl said.

Elliott C. Mendelson, a patent lawyer with Connolly, Bove, Lodge & Hutz in Wilmington who represents the brand-name drug companies, said those trying to read the tea leaves could see Jones' lengthy discussion on development as a bad sign.

Pohl and some other participants scheduled to participate in a November symposium held by the Institute for International Research in Washington, D.C., on combating efforts to delay the availability of generic drugs, said the AstraZeneca decision is likely to generate a lot of discussion.

Another likely topic will be a June ruling by an administrative law judge. In a blow to the generic drug makers, the judge dismissed an anti-competitive action brought by the Federal Trade Commission against Schering-Plough Corp. of Kenilworth, N.J., Upsher-Smith Laboratories Inc. of Minneapolis and American Home Products (now Wyeth) of Madison, N.J. The agency had alleged that Schering-Plough formed agreements with the companies to keep low-cost generic competitors from making its patented potassium chloride product, K-Dur 20.

The judge ruled that patent law confers upon the patent holder the "exclusive right to make, use or sell the patented invention during the patent term" and to exclude others.

Ahaviah Diane Glaser, director of the Prescription Access Litigation project with Community Catalyst, a consumer coalition in Boston, said she could not comment on specifics of the recent AstraZeneca ruling, but agreed the battle between generics and brand-name companies has gotten contentious.

Community Catalyst, whose mission is to bring low-cost generics to the public by "bringing an end to illegal practices engaged in by drug companies," filed class action lawsuits in several states against AstraZeneca and Barr Laboratories of Pomona, N.Y., a year ago.

After challenging AstraZeneca's patent for tamoxifen in 1992, Barr and AstraZeneca settled the matter. AstraZeneca then gave Barr exclusive rights to distribute a generic version of tamoxifen made by AstraZeneca. Since the price is not significantly discounted, Community Catalyst alleges the two companies are engaging in anti-competitive behavior. AstraZeneca and Barr deny the allegations.

With the cost of developing products skyrocketing to $802 million in 2000 from $54 million in 1976 and the period of market exclusivity shrinking for breakthrough products as other brand name drug companies come out with competing products, drug making is extremely high risk, according to the pharmaceutical group.

The FTC study found that brand-name companies generally sued all generic applicants to the FDA if the drug had annual sales of more than $500 million.

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