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Lawsuit: OxyContin illegally marketed, sold

The accusations came after a ruling that certain patents on the drug are invalid.

By **DORIS BLOODSWORTH**
SENTINEL STAFF WRITER

A consumer-advocate group has sued the maker of OxyContin, alleging the company has been marketing and selling the powerful painkiller illegally since it was approved in 1995.

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Filed Tuesday on behalf of patients nationwide, the lawsuit comes a day after a federal judge in New York ruled that certain patents on OxyCon-

tin are invalid because Purdue Pharma misled federal officials while seeking approval from the U.S. Patent and Trademark Office. That decision could have far-reaching consequences.

U.S. District Judge Sidney Stein stated that Purdue had no clinical

studies to support its claim that OxyContin was unique because 90 percent of patients using the controlled-release oxycodone drug got relief taking 10-milligram to 40-milligram-strength tablets.

In his ruling, Stein noted that Dr. Paul Goldenheim, Purdue's executive

PLEASE SEE **OXYCONTIN, A4**

Judge's ruling could open way for cheaper, generic painkillers

OXYCONTIN FROM A

vice president and chief scientific officer, testified that researchers "weren't anywhere close" to proving such claims at the time the company was seeking the patents.

His decision came in a lawsuit filed by Purdue against a competitor, claiming patent infringement. Endo Pharmaceuticals wanted to sell a generic form of OxyContin.

Purdue officials said they would appeal Stein's ruling and expect his decision will be reversed.

"We were surprised and disappointed by the ruling," Purdue's chief legal officer, Howard Udell said in a statement released Wednesday. "While we have great respect for the judge, we feel that in this instance he has ruled in error."

In its statement, Purdue Pharma said it had subsequently proven that its initial claims to patent officials were true.

Legal experts Wednesday said the federal judge's ruling could lead to major changes.

Cheaper generics, already being considered by the U.S. Food and Drug Administration, could soon be in the hands of pain patients who depend on strong medication to function and to get a full night's sleep. That competition could hurt Purdue because OxyContin produced almost \$1.5 billion, or about 80 percent, of the company's sales in 2001.

In addition, the company — which is battling hundreds of lawsuits tied to problems of addiction and overdose from OxyContin — could find itself the target of more lawsuits, such as the one filed by Boston-based Prescription Access Litigation, legal experts say.

The nonprofit group alleges in its lawsuit that Purdue went to "lengths to maintain its monopoly over the drug by suing a generic company to prevent it from putting a less expensive version of OxyContin on the market."

Endo Pharmaceuticals, which has made oxycodone painkillers Percocet and Peccodan for decades, sought approval for its own time-released version in 2000. That sparked Purdue's suit. The federal judge agreed that Endo, based in Chadds Ford, Pa., had infringed on OxyContin patents. But the judge said Purdue's misleading statements invalidated its patents.

John Rizvi, a Fort Lauderdale patent attorney, said other competitors also will view the judge's decision as a "green light signaling that it is now safe to enter the market."

Rizvi said fallout could extend beyond Purdue, a private company in Stamford, Conn.

"Consumer confidence in corporate honesty is already shaken in the wake of Enron," he said. "Inevitable conduct before the patent office may prove no easier for stockholders, employees and others to forgive than fraudulent accounting practices."

Michael Ryan, who represents a Kistimmee woman suing Purdue Pharma in the death of her husband, who was prescribed OxyContin in 2000, called the revelations about Purdue "outrageous."

"The company lied about the efficacy and increased safety of this drug," Ryan said.

"This ruling should inspire attorneys general and prosecutors all over the country to consider what options exist to hold the company responsible for this fraud and the effects on patients," she said.

Some Florida officials said they are looking closely at the ruling.

State Sen. Burt Saunders, who is leading a panel looking into Medicaid and overprescribing problems tied to OxyContin and other prescription drugs, said he wants to look at the federal ruling before the Senate's health committee meets in Orlando on Jan. 26. The meeting, from 4 to 7 p.m. at the downtown Orlando Public

This Court finds, by clear and convincing evidence that a reasonable examiner would have considered important the fact that Purdue did not have any "scientific proof" that the claimed invention actually provided adequate pain relief for most people over a four-fold dosage range to be important information: and that the lack of that proof is inconsistent with Purdue's reduced dosage assertion.

Dr. Goldenheim — to whom Dr. Kaiko directly reported since he started working at Purdue, — testified that as of October 20, 1993, Purdue's researchers "weren't anywhere close" to proving that OxyContin was "the most efficiently titratable long-acting strong analgesic," and these titration claims were "clearly Bob Kaiko's vision."

Accordingly, Endo has proven, by clear and convincing evidence, that Purdue intentionally misrepresented its "discovery" to the PTO.

Ruling. Excerpts from a federal judge's ruling that OxyContin patents were invalid because the company deliberately misled federal officials while seeking approval from the U.S. Patent and Trademark Office.

Library, will give the public a chance to comment.

"This is a major issue because through Medicaid we are spending tremendous amounts on OxyContin," Saunders said. "If it turns out that Purdue misled and kept us from using generics, I would think Florida along with every other state with Medicaid could make a claim for excess payments when generics would have done the same thing." The state paid more than \$80 million in Medicaid payments for OxyContin prescriptions in 2001 and 2002.

A U.S. congressional panel also will hear from the public when it meets in Orlando on Feb. 9. The state and federal hearings come after newspaper reports highlighting problems

tied to, among other drugs, OxyContin.

In October, the Orlando Sentinel reported that deaths in Florida from oxycodone, the key ingredient in OxyContin, exceeded those from heroin. Florida medical examiners reported 573 oxycodone overdose deaths in 2001 and 2002. The paper's review of 500 available autopsy results from the same time period showed that OxyContin was named in 83 percent of the 247 cases in

which a specific oxycodone medication was identified. The exact medication was not determined in the remaining 253 deaths.

Florida Attorney General Charlie Crist, who also is vice chair of a national prescription-pricing task force, is reviewing the federal decision. JoAnn Carrin, his spokeswoman, said it was too early to see what, if any, action Crist might take.

Kathleen Quinn, a spokeswoman for the U.S. Food and

Drug Administration, said her agency likewise was examining the federal judge's ruling "to see if it has any implications for FDA. But ultimately, the ruling is a decision about patents and about representations to the P.T.O. (Patent and Trademark Office), not FDA," she said.

Consumers had mixed reactions to the recent flurry of legal maneuvers. Some worried that problems of addiction and abuse tied to OxyContin could multiply.

But Endo spokesman Bill Newbould said his company would not market its generic drug to consumers or physicians. It will promote it directly to wholesalers and pharmacies.

"We have a comprehensive risk-management plan that we have worked with the FDA on that will include patient- and physician-education programs," said Newbould, who added that the company also is researching a pill that would be abuse-resistant. Purdue officials have said they are researching a similar product.

An Orlando pain patient said he will likely stick with OxyContin even if generic brands are available.

"OxyContin is very powerful, and it has been successful for me," said Chris Bryan, 55, who suffers from dystonia, a painful neurological disorder. "But I really could care less if it's OxyContin or something else. I just want something that will work."

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