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FDA's OxyContin Ruling May Spur New Battles Over Generics

By **Rachel Slajda**

Law360, New York (April 23, 2013, 2:54 PM ET) -- Last week's decision by the U.S. Food and Drug Administration to block generic versions of the oft-abused painkiller OxyContin could embolden makers of other top-selling branded drugs to push the agency to grant them what amounts to a major patent extension by citing safety concerns, drug industry experts say.

Last week, the FDA announced that it would not accept any generic applications based on the original version of Purdue Pharma LP's OxyContin, an opioid painkiller, the same day the patent expired. The agency said it found that the original version, which Purdue stopped selling after it won approval for a more abuse-resistant formulation of the drug, had been pulled due to safety concerns.

It was a groundbreaking and, to many experts, surprising decision by the FDA. It thwarted the plans of Teva Pharmaceuticals and other generics companies that were hoping to cut into OxyContin's $2.9 billion annual market.

"I was surprised. I thought, based on some decisions they've made in the past, which was to stay pretty firmly leaning toward generics on similar kinds of decisions, that they would tell Purdue, 'Thank you very much for making this abuse-deterrent formula, but we're going to approve generics,'" said Rebecca Dandeker, a partner with Morgan Lewis & Bockius LLP who represents generics companies.

"In this very serious pain reliever category, the innovators have been very sophisticated for years about arguing that their products are so unique and dangerous that generics shouldn't be permitted ... and the FDA has considered those arguments and said 'we don't agree,'" she said.

This time was different. Dandeker and others said one major factor was likely political pressure from state attorneys general — 48 signed a letter urging the FDA to make this call — as well as federal, state and local law enforcement agencies and lawmakers from both parties.

Purdue's original OxyContin could be crushed easily, overcoming its extended-release mechanism, and snorted or injected. Its newer version is harder to crush and inject. The FDA's ruling means the country won't see generics of OxyContin until the newer version comes off patent, which, barring successful patent challenges, will come in 2025.

Drug law experts said they were concerned that the decision is not a one-off but the beginning of a trend. The FDA could begin effectively requiring abuse deterrents on more addictive painkillers, or even expand similar thinking to drugs with other safety concerns, they said.

“I think the FDA will seek to exercise this authority in more cases,” said Richard Scheff, chairman of Montgomery McCracken Walker & Rhoads LLP, who represents branded companies. “I don't think it could be limited to just drugs that are potentially abused on the streets, but could be extended to other areas. That's the risk here. You're seeing, perhaps, the extension of FDA authority.”

“If it ends up hurting generics because it takes longer to compete, those are significant dollars,” he said.

The FDA is weighing how to encourage drugmakers to incorporate abuse deterrents into their formulations. The agency released a guidance document in January outlining how drug sponsors should test deterrents and how the FDA will evaluate them, and said it will hold a public meeting on the subject later this year.

The precedent it set in the OxyContin decision could be expanded without new rules, experts say.

"The wider implication and the problem is, where does it stop? Today it's OxyContin. Tomorrow they could pick off another two or three. ... Pretty soo,n all drug manufacturers are required to formulate with abuse-deterrent technology. Costs go up for everybody,” Dandeker said.

Purdue's strategy — asking the FDA for a ruling that it pulled its original, FDA-approved OxyContin for safety reasons in order to delay generics — will be attempted by other innovators, experts say.

"Innovators are sophisticated at using these situations to their advantage. I can just withdraw my drug, say it was for safety reasons, and come out with a new one. And now FDA's in a quandary because it has a precedent,” Dandeker said. “Pretty soon there won't be generics in any abuse-prone pain relievers."

“Maybe the FDA looked at this and said, that's OK, we think cutting down on abuse is the more important factor,” she added.

--Editing by John Quinn and Richard McVay.