

Generic Drug Litigation: A Growing Practice Niche

Hartford firm wins rare court victory over FDA

By JAY STAPLETON

We've all heard about the "fiscal cliff," the combination of federal government spending cuts and tax increases expected to kick in early next year that, some experts say, could have dire consequences for the economy. But fewer have heard about the "patent cliff" currently wreaking havoc on the pharmaceutical industry.

Between 2011 and 2015, the patents on many blockbuster, brand-name drugs are set to expire, which would allow lower priced generic equivalents to move into the market and take sales away from pharmaceutical firms. At stake are, by some estimates, as much as \$250 billion in worldwide sales. There is no disputing this is a ripe area for litigation.

A Connecticut law firm is building a growing practice helping generic drug makers win Food and Drug Administration approval for their products. That firm, Hartford's Axinn, Veltrop & Harkrider, and specifically partner Chad Landmon, recently notched a big victory over the FDA on behalf of the maker of a generic diabetes drug.

"The rush to develop generic products is much more intense than it ever was before," Landmon said. "Our firm is building a niche in its FDA practice."



Michael Cantor

Hartford-based Cantor Colburn also has attorneys that assist generic drug companies bring products to market. "Generic pharmaceutical litigation is a significant and fast-growing practice area," said partner Michael Cantor in a 2010 news release announcing the hiring of two lawyers that handle such cases.

Major pharmaceutical makers like Pfizer Inc. or Boehringer Ingelheim — just to name two firms with a strong Connecticut presence — spend millions of dollars on performing research and development, field-testing medications and shepherding them through the FDA approval process. To ensure a return on their investment,

the companies receive a 20-year patent on the drugs.

But that number is deceiving. The patents are often obtained long before the drugs actually reach market, and so the effective length of many patents is more in the seven- to 12-year range, according to some estimates. Also, a patent doesn't guarantee market exclusivity. Although federal law in this area is exceedingly complicated, generic drug companies can apply to the FDA to manufacture their own version years before a patent expires.

Beyond that are other twists and turns. Brand-name pharmaceutical makers frequently file patent infringement suits to try to extend their own exclusivity period. Sometimes they attempt to extend their patents by making slightly different versions of a drug. Further, generic drug manufacturers can apply for their own 180-day period of exclusivity for marketing and selling a previously-patented medication. The exclusivity window is vital to drug makers. It's during that time when they can reap the biggest profits.

Against this backdrop, those who practice in this area of law took note of Landmon's legal victory. Last month, U.S. District Judge Amy Berman Jackson in Washington, D.C., found the

FDA incorrectly interpreted the law when it denied Landmon's client, Watson Laboratories Inc., permission to sell the diabetes drug Actos and to have a 180-day period of exclusivity.

"The decision is big news: it is the first time a court has ever ordered FDA to approve a marketing application for a drug," wrote the FDA Law Blog, which is produced by the Washington, D.C., firm of Hyman, Phelps & McNamara.

Accelerated Application

The stakes, as in all pharmaceutical litigation matters, were high. Actos, a leading drug used for treating type 2 diabetes, had \$2.7 billion in sales last year.

In July 2003, Landmon's client, Watson Pharmaceuticals filed the required "accelerated new drug application," or ANDA, with the FDA to market a generic version of the diabetes medication. Takeda Pharmaceutical Co., which holds the patent, responded by filing a lawsuit against Watson. A settlement was reached in 2010, giving Watson and a second company, Mylan Inc., a green light to start selling generic versions in September 2012.

But earlier this year, the FDA informed Watson that it was switching gears and had decided to grant approval only to Mylan. So Watson filed suit against the agency, claiming that the "FDA failed to provide any explanation or basis for its determination."

At the heart of the case is the Hatch-Waxman Act, the 1984 law that governs how pharmaceutical patents are approved and seeks to reduce delays for companies that market lower cost, generic medication.

Court records indicate that the FDA based its denial of Watson's application on a timing issue. In short, while Watson was first to file an initial application

to market the generic drug, Mylan was the first to file an amended application as required. FDA lawyers argued that the agency had discretion to determine which generic drug company had correctly followed the law during the application process.

Landmon initially sought a temporary restraining order that would have prevented the FDA from granting final approval to any other generic drug maker seeking to market the diabetes medication. Rebuffed by the judge, he pushed forward with a motion for summary judgment in Watson's lawsuit.

The FDA rarely loses such challenges, in part because Hatch-Waxman calls for courts to defer to the agency in interpreting the law. But Judge Jackson ruled that the FDA had misinterpreted the law, that Watson had followed all the proper procedures and that it was "arbitrary and capricious for FDA to deny Watson."

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Under the ruling, both Watson and Mylan are now authorized to market the drug and will share the 180-day exclusivity window, after which other drug makers can enter the market. "It was never about knocking Mylan out," Landmon said. "It was about including Watson."

The FDA has appealed the decision to the U.S. Court of Appeals for the District of Columbia Circuit. Washington D.C. The agency did not respond to a request for comment.

Landmon, a University of Connecticut School of Law graduate, joined

the Hartford office of Axinn, Veltrop & Harkrider about 12 years ago. Partner James D. Veltrop says while the firm used to represent mostly makers of name-brand drugs, the practice has shifted over the years toward more generic pharmaceutical companies.

The firm, for example, represents the Actavis Group, one of the world's largest generic pharmaceutical companies.

Landmon has established himself as a go-to person at the firm for Hatch-Waxman Act cases, handling one or two new cases a year. While there is no discovery in such cases, there are typically thousands of pages of administrative records to pore through.

Unlike the complex patent litigation and antitrust cases he also handles, Landmon said the FDA lawsuits over generic drug approval are fast-moving, typically involving a motion for summary judgment and legal argument. For instance, the Watson case went

from filing to decision in two months.

"I guess what I really enjoy is how complicated the cases can be, from both the legal perspective and a factual perspective," he said. "And the fact that there is so much strategy involved not only in the patent suit but also in dealing with FDA. You really need to consider it all." ■