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# Firm Gears Up For High-Stakes Drug Lit

## Axinn, Veltrop wins victory for generic pharmaceutical maker

**By THOMAS B. SCHEFFEY**

It can cost pharmaceutical companies hundreds of millions of dollars—or more—to develop a new prescription drug. Still, the investment can reap mind-boggling dividends.

For example, Aricept, the leading medication used to fight Alzheimer's disease, reaps $1 billion a year for its maker, Tokyo-based Eisai. The drug is distributed in this country by Pfizer Inc., which has extensive research facilities in Groton.

With so much at stake, it's little wonder that U.S. courts are teeming with lawsuits filed by big pharmaceutical companies defending their patents against generic drug manufacturers that want to make essentially the same drug—and sell it for less.

Into this fray wades the intellectual property and complex litigation firm of Axinn, Veltrop & Harkrider, which has a Hartford office. The office just announced the hiring of four more attorneys as it positions itself to be an even bigger player in pharmaceutical patent cases.

One new associate, Ti Chen, previously worked for the pharmaceutical industry.

An associate promoted to partner, Chad Landmon, has expertise in the Hatch-Waxman Act, the 1984 federal law that governs pharmaceutical patents.

Hartford partner James D. Veltrop explained that while the firm used to mostly represent makers of name-brand drugs, the practice is shifting toward generic clients. The firm, for example, represents the Actavis Group, one of the world's largest generic pharmaceutical companies.

"We've had a steady stream of pharmaceutical patent lawyers moving from all over—New Jersey, Chicago, D.C.," said Veltrop. "We've got a huge shop here that does patent litigation, and the bulk of it is pharmaceutical patent litigation.

James D. Veltrop and James P. Doyle, of Axinn, Veltrop & Harkrider represent a drug company that wants to make a generic version of the world's best-selling Alzheimer's drug. They recently won dismissal of a patent infringement suit fild by the Japanese company that now makes the drug.

Since 1999, Axinn, Veltrop & Harkrider has been counseling clients and litigating matters involving the Hatch-Waxman Act.

### Golden Goose

Veltrop and James P. Doyle, another partner in the firm, recently won a significant case for another generic drug client, Mutual Pharmaceutical Co. of Philadelphia, which is exploring the manufacture of a generic version of Aricept in a soluble pill form.

Their case has attracted widespread attention from industry lawyers for generic and brand-name drugs alike.

Eisai holds the patent for Aricept until 2010, and is understandably protective of its golden goose. Strategically, the holders of sunsetting drug patents want their prospective competitors under court scrutiny sooner, rather than later, the better to monitor the high-stakes end of the patent's life.

And so Eisai filed a patent infringement suit even before Mutual began making the drug.

Paul Pescatello, president of Connecticut United for Research Excellence, or CURE, the state's New Haven-based bioscience organization, is not surprised that companies such as Eisai mount vigilant defenses, given the stakes involved.

"It costs between $850 million and $2.5 billion, on average, to produce a marketable drug these days, and that cost is reflected in the market cost of the product," said Pescatello, who noted that the Connecticut pharmaceutical industry employs more than 20,000 people.

**Blockbuster drugs going generic create a high-stakes end game.**

## Fast-Track Procedure

In 2002, Mutual filed an application with the Food and Drug Administration to produce Aricept's active ingredient, using an expedited procedure created by the Hatch-Waxman act. Congress passed the law after a drug Goliath used FDA and patent law to cudgel a generic David. The big company won a patent infringement action, paralyzing its small, would-be rival at a point when it was simply experimenting with the idea of producing a generic.

In reaction, Hatch-Waxman allows fast-track applications for post-patent generics, to reduce expensive delay. The new rules allowed the FDA to take into account the brand-name drug's history of safety and effectiveness, which spares the generic company from having to repeat long, costly drug trials.

Congress created a concession to the major pharmaceutical manufacturers in the form of a legal fiction. Hatch-Waxman made the very act of filing the fast-track application a new kind of patent infringement, in most cases. As soon as a generic applicant formally declares that its proposed product won't infringe—long before it had any product to launch—the brand company can test that claim in court.

The fast-track procedure is known as an "accelerated new drug application," or ANDA.

Because Mutual's ANDA didn't specify when it would start production of the Alzheimer's drug, Eisai assumed the worst. Claiming infringement, it filed suit in August 2006.

The Hatch-Waxman Act references the FDA's list of currently produced drugs, the so-called Orange Book. Patent holders with products listed in the Orange Book bring most, but not all, Hatch-Waxman actions. Federal courts have split on whether Orange Book listing is a precondition for a Hatch-Waxman patent infringement action.

Eisai—repeatedly, in 2003 and 2005—managed to file the wrong form with the FDA for its orally-dissolving form of Aricept, which kept it from being listed in the Orange Book. Mutual, therefore, wasn't legally on notice about the patent, and made no reference to it in its ANDA.

The New Jersey federal judge Harold A. Ackerman, in a 45-page analysis, held that an ANDA filing by a generic drug company doesn't authorize a brand-name drug maker to sue for patent infringement unless two things have happened.

First, the drug patent must be listed in the Orange Book. Second, the generic manufacturer must have formally claimed it is not infringing. Neither happened here, and the judge dismissed the suit.

Ackerman's ruling conflicts with several federal decisions that have allowed Hatch-Waxman suits for drugs not in production, or otherwise not listed in the Orange Book. Veltrop noted, "There are many cases across the country involving manufacturing process patents or therapeutic use patents that do not appear in the Orange Book, and this decision calls into question whether those suits remain viable."

Eisai, as a backup strategy, also asked Ackerman for a traditional declaratory judgment action to prevent patent infringement. It said it feared imminent harm from a product launch by Mutual. However, in a court-sanctioned agreement, Mutual had promised to give Eisai 45 days notice before any product launch. For that reason, Ackerman concluded the threat of infringement wasn't sufficiently pressing, and dismissed the case on both grounds.

William J. Heller, of McCarter & English in Newark, represents Eisai. He declined comment, referring questions to lead counsel Bruce M. Wexler, of Paul, Hastings, Janofsky & Walker in New York. Wexler said he could not comment.

As for the future, Veltrop plans on having enough pharmaceutical work to keep his new hires busy. With so many medical breakthroughs in recent decades, the rate of creation of blockbuster drugs is actually declining. But that just means ever more fierce legal battles over those that are developed.

"The stakes become higher as there are fewer and fewer product to make the [financial] numbers with," Veltrop said. ■