

Life Sciences Group Of The Year: Paul Hastings

By **Kelly Knaub**

Law360, New York (January 13, 2014, 4:05 PM ET) -- Paul Hastings LLP's precedent setting victory for Sunovion Pharmaceuticals Inc. and its representation of Avalon Ventures in the formation of a \$495 million venture fund, among other key wins and high-end work in 2013, earned the firm a spot on Law360's list of Life Sciences Practice Groups of the Year.

The firm represented Sunovion in its case against generic-drug company Dr. Reddy's Laboratories, accused by Sunovion of infringing four patents by seeking approval to market generic versions of the prescription branded sleep aid Lunesta.

Sunovion's patent covers a compound that contains less than 0.25 percent a certain type of impurity. Dr. Reddy's had sought approval from the U.S. Food and Drug Administration for a generic version with a level of impurity between zero and 0.6 percent, and submitted a document to New Jersey federal court stating that — despite what it said in the abbreviated new drug application — it would not market a product that contains less than 0.3 percent of the impurity and thus would not infringe.

Joseph O'Malley, New York-based co-chair of Paul Hastings' intellectual property practice and lead attorney on the case, said that after the district court issued a “bizarre order” granting Dr. Reddy's summary judgment of noninfringement last January, the firm focused its energy on preparing its appeal.

“We went from the docketing of the appeal to argument in two and a half months,” O'Malley said. “We needed a decision by the end of this year and we got it.”

In September, the Federal Circuit flipped the district court judge's decision and held that the company's ANDA infringed Sunovion's patent, and that under the Hatch-Waxman Act, the filing of the ANDA itself constituted infringement, making new law.

Since Sunovion's patent was set to expire on Dec. 31, and the FDA would have been able to approve Dr. Reddy's ANDA, the firm then raced against the clock to get a mandate that would formally reverse the noninfringement judgment.

O'Malley described it as an “all-out mad war,” with Sunovion trying to run the clock past Dec. 31 and the firm doing everything possible to get the final decision, and if not, a preliminary injunction.

A mandate was issued in December, and on Jan. 13, an injunction was issued barring the FDA from approving the ANDA until April 15, 2014. O'Malley said that each day of exclusivity for Sunovion is worth

about \$1 million per day.

The firm previously scored a victory that vacated a district court's finding that two patents held by Galderma Laboratories Inc. for the rosacea drug Oracea were invalid, which affirmed the validity and infringement of the longest running patent-in-suit and protects the company's branded drug through 2027.

On the corporate side of Paul Hastings' life sciences work, attorneys represented Avalon Ventures in April in the formation of a \$495 million venture fund with GlaxoSmithKline PLC that will launch up to to 10 early-stage life sciences companies.

Rob Carlson, Palo Alto-based chair of the transactional side of the life sciences group, said that the most challenging aspect of a transaction of this kind is worrying about the regulatory tax and other issues involved in structuring the funds. But Carlson said the firm's national and international corporate and tax capabilities enable the group to do the sophisticated work efficiently.

The collaboration was a novel idea in that it's a new way to fund research and drug therapies, Carlson said.

Carlson also represented biotech company Capricor Inc. in a complex stock-for-stock reverse merger with Nile Therapeutics Inc., which was completed in November. The corporate attorney said the toughest part of the transaction was structuring the deal so the former Capricor shareholders who were receiving Nile shares were adequately protected and making sure the company would comply with its U.S. Securities and Exchange Commission obligations, both for the deal and going forward.

In June, Paul Hastings corporate attorney Carl Sanchez, who landed on Law360's list of MVPs, advised biotech company Ardea Biosciences Inc. on its well-publicized \$1.2 billion sale to industry titan AstraZeneca PLC.

The firm's life sciences group, which has more than 50 attorneys that practice life sciences on a regular basis, comprises a focus for the firm itself.

"It's important to the U.S. economy and the world economy and we try to focus our groups on the companies that are providing novel therapies to patients," Carlson said.

According to O'Malley, the life sciences IP group at the firm has never lost a case in its seven-year existence.

"We've been a part of more of the iconic life sciences IP cases," he said.

--Additional reporting by Ryan Davis and Karlee Weinmann. Editing by Andrew Park.