

Teva Invalidates Opiant Patents In Narcan Suit

By **Dave Simpson**

Law360 (June 5, 2020, 10:43 PM EDT) -- A New Jersey federal judge found that claims from four patents related to Narcan, the nasal spray treatment for opioid overdoses, are invalid Friday, handing a win to Teva Pharmaceuticals USA Inc. in a suit from the treatment's licensor and licensee Opiant Pharmaceuticals Inc. and Adapt Pharma Operations Ltd.

While the opinion was sealed, an order from U.S. District Judge Brian R. Martinotti indicated that he invalidated claims from U.S. Patent Nos. 9,468,747, 9,561,177, 9,629,965, and 9,775,838 following a two-week bench trial beginning on Aug. 26 and concluding on Sept. 6, with experts testifying in October and closing arguments in February.

Adapt and Opiant sued Teva in October 2016, saying that Teva's application to sell a generic version of Adapt's Narcan infringes the drug's patent.

Adapt said that the new drug application for a generic Narcan, which is the first U.S. Food and Drug Administration-approved nasal spray for the emergency treatment of known or suspected opioid abuse, infringes a patent for which it is the exclusive licensee. The claims of the first patent-in-suit, which is owned by Opiant, cover the device, the composition and the formulation of Narcan.

Teva had submitted an abbreviated new drug application for a generic version of naloxone hydrochloride nasal spray, which Adapt and Opiant said infringed the patents in questions

Unless stopped by the court, if the FDA approves Teva's ANDA, it will infringe one or more claims of the patents by making, using, offering to sell, selling or importing the product in the U.S., Adapt and Opiant said. By doing so, Teva would intentionally and knowingly encourage direct infringement of the patent, because it knows that the generic is specifically adapted for use that infringes the patents and that there's no substantial noninfringing use for the proposed product, Adapt said.

Upon submitting its ANDA, Teva told the FDA that it believed the patents' claims are invalid, unenforceable or won't be infringed by the application, Adapt said.

Teva also told Adapt and Opiant of the application in mid-September 2016, offering to provide access to certain confidential information within the ANDA, but the parties didn't reach an agreement and Teva hadn't provided any of that information, Adapt said in its suit.

Narcan is used to temporarily reverse the effects of opioid medicines and has no effect in people who are not taking opioid medicines. Emergency medical help is still necessary after the first dose, according to the drug's website.

Representatives for the parties did not immediately respond to requests for comment Friday.

Adapt and Opiant are represented by Charles H. Chevalier and J. Brugh Lower of Gibbons PC.

Teva is represented by Liza M. Walsh, Hector D. Ruiz, Eleonore Ofosu-Antwi and William T. Walsh, Jr. of Walsh Pizzi O'Reilly Falanga LLP and J.C. Rozendaal, Michael E. Joffre, Paul A. Ainsworth, Chandrika Vira, Adam C. LaRock, Jean Paul Y. Nagashima, Sasha Rao, Michael Bruns and Matthew Mahoney of Sterne Kessler Goldstein & Fox PLLC.

The case is Adapt Pharma Operations Ltd. et al. v. Teva Pharmaceuticals USA Inc. et al., case number 2:16-cv-07721, in the U.S. District Court for the District of New Jersey.

--Editing by Jay Jackson Jr.