

## Obviousness Doomed Narcan Patents After NJ Bench Trial

By **Dani Kass**

*Law360 (June 23, 2020, 9:22 PM EDT)* -- Teva Pharmaceuticals proved that claims from four patents covering Adapt Pharma's opioid overdose medication Narcan are obvious, and the drug's success can't override that finding, a New Jersey federal judge said in an opinion unsealed Monday.

U.S. District Judge Brian R. Martinotti's 97-page opinion came about two weeks after releasing a summarized order with his validity findings from the bench trial. The decision was unquestionably in favor of Teva, which had been accused of infringing the patents with its proposed generic version of the drug.

"The court finds that there is clear and convincing evidence the asserted claims of the patents-in-suit are obvious in light of the prior art," the opinion concludes.

The prior art analysis looked at whether a higher dose of naloxone, the drug in Narcan, would have been safe and effective and if it otherwise would have been an improved intranasal drug compared to what was already known.

Judge Martinotti said the prior art made clear that naloxone was "an extremely safe drug" that could be inserted through the nose, and that even the higher dose patented by Adapt was within the realm of what was known to be safe.

The prior art made clear how to best provide naloxone in a community setting, where the rescue medication was meant to be given, as opposed to a health care setting where it could be injected with a needle, the judge said. Since the drug was safe, providing a high dose from the onset was foreseen by prior art, so a lay person wouldn't have to worry about providing a second dose or other medical treatment, like rescue breathing, for which they're not trained, Judge Martinotti added.

Adapt had said a piece of prior art would have encouraged people not to use a particular preservative that it included, but the judge disagreed. He said that preservative was often used in nasal formulations, and that the prior art that discouraged its use has been questioned.

Judge Martinotti then shot down arguments from Adapt that there were secondary considerations that proved the patent claims aren't obvious.

Among them, the judge concluded that there were no unexpected results in Adapt's invention, that

third-party praise was tied to parts of the invention disclosed in prior art, and that there wasn't a long-felt but unmet need for a needle-free naloxone product that lay people could easily use. And while the product has been successful, the judge said it wasn't because the invention wasn't obvious.

"The court finds that Narcan's commercial success is attributable to the features already known in the prior art, Adapt's marketing strategies and tactics, and Narcan's strategic pricing, rather than the alleged novel features of the patents-in-suit," he said.

Emergent BioSolutions Inc.-owned Adapt had sued Teva alongside Opiant Pharmaceuticals Inc., which owns the patents and licenses them to Adapt. Narcan brought in \$280 million for Emergent in 2019, according to the company's financial filings.

The 2016 suit had gone to trial in August, featured October expert testimony and February closing arguments.

Counsel for the parties didn't immediately respond to requests for comment Tuesday.

The patents-in-suit are U.S. Patent Nos. 9,468,747; 9,561,177; 9,629,965; and 9,775,838.

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 Adam LoBelia.

*Update: This story has been updated with additional counsel for Teva.*

All Content © 2003-2020, Portfolio Media, Inc.