

## **J&J Unit Beats Schizophrenia Drug IP Challenge On Remand**

By **Adam Lidgett**

*Law360 (December 18, 2024, 8:52 PM EST)* -- Teva Pharmaceuticals USA Inc. has failed to invalidate claims in a patent for a Johnson & Johnson unit's blockbuster schizophrenia medicine, according to a New Jersey federal judge who rejected the generic-drug maker's assertions that the formula was obvious.

In an opinion unsealed Tuesday, U.S. District Judge Claire C. Cecchi found that Teva failed to show any of the challenged claims in U.S. Patent No. 9,439,906 are invalid, handing a win to Johnson & Johnson in a suit over its drug Invega Sustenna. The opinion was initially released under seal in late November, and it is already the subject of an appeal, according to court records.

"Teva fails to carry its burden to prove that a [person of ordinary skill in the art] cognizant of the prior art would have a reasonable expectation of success in achieving the claimed dosing regimen" outlined in one of the patent claims relating to a regime for a patient that doesn't have a kidney impairment, Judge Cecchi wrote.

Mylan Laboratories Ltd. was also sued, but agreed to be bound by whatever the outcome of the instant case is, according to court documents.

While Teva said an ordinarily skilled person would be motivated to change a dosage regimen outlined in prior art to achieve the same dosage regimen as the one outlined in two other claims relating to patients who have kidney impairments, the judge said, "Teva fails to prove a motivation to reduce [the] dosage" in a way that would match those claims.

Invega Sustenna and its related versions had U.S. sales of \$2.9 billion in 2023, according to a Johnson & Johnson press release from January. The unit of the company that owns the patent changed its name last year from Janssen Pharmaceuticals to Johnson & Johnson Innovative Medicine.

The patent covers a dosing regimen for a long-acting version of Invega Sustenna that is injected into the muscles on a schedule ranging from monthly to every six months. The patent says that it is an improvement over tablet versions that must be taken daily.

The suit made its way back to the federal district court after a Federal Circuit panel in April revived Teva's attempt to argue the patent was invalid, arguing the lower court initially used an "erroneously rigid" analysis when rejecting Teva's challenge. Specifically, the appeals court faulted numerous aspects of a 2021 decision by Judge Cecchi that the generic-drug maker failed to show that several claims of the patent are invalid as obvious.

Counsel for the parties did not immediately respond to requests for comment from Law360 on Wednesday.

The patent-at-issue is U.S. Patent No. 9,439,906.

Janssen Pharmaceuticals is represented by Barbara L. Mullin, Andrew D. Cohen, Aron Fischer and J. Jay Cho of Patterson Belknap Webb & Tyler LLP, and Keith J. Miller and Michael J. Gesualdo of Robinson Miller LLC.

Teva Pharmaceuticals is represented by John C. O'Quinn, William H. Burgess, Christopher T. Jagoe, Noah S. Frank and Jeanna Wacker of Kirkland & Ellis LLP, and Liza M. Walsh and Christine I. Gannon of Walsh Pizzi O'Reilly Falanga LLP.

Mylan is represented by Deepto Mukerjee and Lance Soderstrom of Katten Muchin Rosenman LLP, and Arnold B. Calmann and Katherine A. Escanlar of Saiber LLC.

The suit is Janssen Pharmaceuticals Inc. v. Teva Pharmaceuticals USA Inc., case number 2:18-cv-00734, in the U.S. District Court of the District of New Jersey.

--Additional reporting by Ryan Davis. Editing by Amy French.