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Janssen Prevails In Patent Battle With Mylan Over Generics

By **Hailey Konnath**

Law360 (May 23, 2023, 11:08 PM EDT) -- A New Jersey federal judge has ruled that Mylan cannot pursue a generic version of Janssen's schizophrenia drug Invega Trinza, finding that although the patent for Trinza has expired, Mylan's generic would cause physicians to infringe another Janssen patent covering the drug's dosing regimen, according to an order unsealed Tuesday.

Following a bench trial, U.S. District Judge Evelyn Padin entered judgment against Mylan Laboratories, holding that Janssen Pharmaceuticals has demonstrated by a preponderance of the evidence that Mylan's proposed generic and its label "will inevitably induce infringement." On top of that, Mylan has failed to show that Janssen's patent is invalid, according to the 74-page decision, dated May 15.

The judge noted that Mylan's proposed labels "expressly instruct" health care professionals to infringe the patent for patients who missed a dose. Inevitably, patents will miss a dose and thus will need to be reinitiated using Janssen's patented dosing regimen, she said.

"Mylan's proposed labels essentially duplicate Janssen's and recite each limitation of the asserted claims," she said.

Notably, the judge rejected Mylan's argument that its proposed labels discourage infringement by warning that missed doses should be avoided.

"The proposed labels discourage missed doses, but do not discourage or make optional the practice of the asserted claims (or any claimed steps) in the inevitable situation that doses are missed," she said.

Trinza is an injectable, long-acting "paliperidone palmitate" for treating schizophrenia and similar conditions, according to the order. Each injection lasts about three months, per the company.

Mylan had hoped to use the Abbreviated New Drug Application process to market a generic version of the drug substantively identical to Trinza, Judge Padin said.

Janssen's active patent covers a dosing regimen to reinitiate patients to the drug after they missed a dose. But Mylan argued that the patent is invalid and the reinitiation dosing regimen shouldn't be protected by patent law. In particular, Mylan argued that a person of ordinary knowledge in pharmaceutical development could have formulated the patent's claims using information publicly available before the patent was issued.

Judge Padin disagreed, noting that because the claims were approved by the U.S. Patent and Trademark Office, they are "generally presumed valid." Regardless, it appears that the patent examiner indeed conducted searches on prior art, according to the decision.

Ultimately, Mylan has failed to demonstrate that a skilled artisan would have reason to combine prior art references and that one would have a "reasonable expectation of success from doing so," the judge said.

"The court agrees with Janssen that Mylan's obviousness case can be best characterized as a 'hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention,'" she said.

She added that the patent asserts a "unique combination of elements."

Judge Padin also shot down Mylan's contention that many patients will not, in fact, be treated according to those asserted claims. This theory "lacks any legal or factual basis," Judge Padin said.

Janssen won approval from the U.S. Food and Drug Administration for Trinza in May 2015. The company has similarly battled Teva Pharmaceuticals over its attempt to manufacture and sell a generic version of Invega Sustenna. It filed suit against Teva in January 2018.

Janssen sued Mylan in September 2020, according to the case docket.

Janssen and Mylan didn't immediately respond to requests for comment late Tuesday.

The patent-in-suit is U.S. Patent No. 10,143,693.

Janssen is represented by Keith J. Miller and Michael J. Gesualdo of Robinson Miller LLC and Barbara L. Mullin, Aron R. Fischer, Andrew D. Cohen, Lachlan Campbell-Verduyn, A. Robert Quirk, J. Jay Cho and Joyce L. Nadipuram of Patterson Belknap Webb & Tyler LLP.

Mylan is represented by Deepro R. Mukerjee, Lance A. Soderstrom, Brian Sodikoff, Jillian M. Schurr, Jitendra Malik and Joseph M. Janusz of Katten Muchin Rosenman LLP and Arnold B. Calmann, Jeffrey Soos and Katherine A. Escanlar of Saiber LLC.

The case is Janssen Pharmaceuticals Inc. et al. v. Mylan Laboratories Ltd., case number 2:20-cv-13103, in the U.S. District Court for the District of New Jersey.

–Additional reporting by Kevin Penton and Britain Eakin. Editing by Michael Watanabe.
