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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Drug Cos. May Rethink Patent Strategy After Fed. Circ. Ruling

By **Matthew Bultman**

Law360 (November 13, 2019, 8:48 PM EST) -- A recent Federal Circuit ruling could reinvigorate certain types of challenges to pharmaceutical patents and force drugmakers to rethink the way they go about protecting some inventions, attorneys say.

The court late last month invalidated an Idenix hepatitis C treatment patent, upholding a Delaware federal judge's decision that the patent didn't adequately explain how to make the treatment. The court also said the patent lacked a sufficient written description.

The ruling was notable in that it affirmed a decision to overturn a jury verdict requiring Gilead to pay over $2.5 billion for infringement — the largest patent verdict in U.S. history. But attorneys say the ruling could have deeper implications in infringement disputes and potentially alter the patenting strategies of drug companies.

"This could be a really significant change in the way chemical and pharmaceutical patent applications are drafted, filed and prosecuted," said Matthew Dowd, a Dowd Scheffel PLLC partner and George Washington University Law School professor.

Reinvigorating Section 112 Challenges

Idenix and Gilead were at the center of what was described in court documents as an "epic race" to cure the hepatitis C virus. In 2013, Idenix, a subsidiary of Merck & Co., filed a patent infringement lawsuit that implicated Gilead's blockbuster medications Sovaldi and Harvoni.

Idenix's patent covers a treatment using a compound called nucleoside having a certain chemical structure. Included in the patent are a limited number of examples of variations on the compound that were tested.

The problem, according to Gilead, was that the Idenix patent swept "far more broadly than the company's existing research." It said there were billions of additional formulations that fell within the scope of the patent.

"The specification offers no guidance as to which of those billions of modified nucleosides actually are effective against HCV," Gilead wrote in court filings. "It just launches researchers into a hunt for a needle in a hayfield."

In a split decision Oct. 30, a Federal Circuit panel said the amount of testing needed to find that needle led it the conclusion that the patent failed to meet a requirement that patents teach others how to make the invention without “undue experimentation.”

The court also said the patent lacked an adequate written description because it doesn’t demonstrate that Idenix was in possession of a specific group of nucleosides that are effective in treating hepatitis C, including those that are the basis for Gilead’s allegedly infringing treatment.

“They claimed broadly enough to cover what the infringer was doing,” said Kevin Noonan, a partner at McDonnell Boehnen Hulbert & Berghoff LLP. “But the problem is they didn’t enable making that and they didn’t disclose it. They didn’t describe it.”

Dennies Varughese, a director at Sterne Kessler Goldstein & Fox PLLC, said patents covering pharmaceutical compounds are not often challenged on the ground that they don’t meet enablement and written description requirements, which are outlined in Section 112 of the Patent Act.

This is in part because there has been a belief that a general description of the compound can satisfy disclosure requirements, attorneys said. The Federal Circuit’s ruling in the Idenix case challenges those assumptions.

“This could reinvigorate companies taking a hard look at 112 challenges to compound patents,” said Varughese, adding that the ruling gives “practitioners a pretty good road map of how to challenge a compound under 112.”

More generally, Dowd said the ruling continues a trend in the court of what can be seen as an overlap between the analysis for written description and the analysis for enablement.

“The court has, for better or for worse, basically reduced the analysis down to very similar considerations in terms of how many working examples have been provided, how much experimentation is necessary, how broad the claims are,” Dowd said.

Federal Circuit Judge Pauline Newman dissented from the panel ruling, saying the majority had a “flawed theory of Section 112.” Judge Newman said the ruling, which was designated precedential, "provides a new path of uncertainty and unreliability" for patents.

Eyes on the USPTO

Idenix’s patent isn’t an outlier in the pharmaceutical context. Attorneys say it’s not uncommon for a compound patent to include a limited number of working examples, while the claims broadly cover many additional variations. The ruling is a warning against reaching too far.

“What it tells you, especially now: Don’t overclaim,” Noonan said.

The Federal Circuit cited its 2013 decision in Wyeth v. Abbott, which invalidated a patent covering a treatment for a condition known as restenosis. The court in that case similarly found the patent does not allow someone to make the treatment without undue experimentation.

“These are significant cases because they continue a trend of requiring patent owners, inventors and

applicants to provide much more evidence of actual work done to support broad claims to chemical compounds and the uses thereof," Dowd said.

The next question is how the USPTO will respond to the decision. Dowd suggested one outcome could be that patent examiners require companies to include more examples of compounds that are made and tested in a patent application.

But that comes with its own potential downsides for companies.

Testing additional compounds, for example, can take time. In a competitive market, such as the race to cure hepatitis C, any delays could be the difference between a drugmaker being the first to file its application and getting beat by a rival.

"Many of the effects of this decision may hinge on how the patent office and the examiners implement it during the prosecution process," Dowd said.

--Editing by Jill Coffey and Alanna Weissman.