

Fed. Circ. Finds No Standing For Appeal Of PTAB Drug Ruling

By Ryan Davis

Law360, New York (January 9, 2017, 5:09 PM EST) -- The Federal Circuit ruled Monday that medical research company Phigenix cannot appeal an inter partes review decision upholding a patent it challenged on a Genentech cancer drug, marking the first time the appeals court has set standing rules for appealing agency decisions.

The Federal Circuit said that Phigenix Inc. did not show that it would be injured by the patent, which ImmunoGen Inc. licenses to Genentech Inc. to make the breast cancer drug Kadcyla. As a result, the court said Phigenix has no standing to appeal the PTAB's 2015 decision that the company failed to prove that the patent is invalid.

"Because Phigenix has not offered sufficient proof establishing that it has suffered an injury in fact, it lacks standing to bring suit in federal court," the Federal Circuit wrote.

Phigenix argued that the existence of ImmunoGen's patent interfered with its own patent licensing efforts, but the appeals court said that did not show there is a "case or controversy" between the companies, as required for standing by the U.S. Constitution. It therefore dismissed Phigenix's appeal.

The court said that even though the America Invents Act states that a party to an inter partes review who is dissatisfied by the PTAB's decision may appeal to the Federal Circuit, that statement "does not necessarily establish" that such a company has standing in federal court.

In order to make its decision, the Federal Circuit had to establish standing requirements for appealing decisions by a federal body like the PTAB, something it said it had never done before.

"In the nearly thirty-five years since the court's inception, we have not established the legal standard for demonstrating standing in an appeal from a final agency action," it noted.

The court held that the party appealing the decision has the same burden of introducing enough evidence of standing as a plaintiff seeking summary judgment in district court, must support its position with evidence from the record or additional submissions and must do so at the "first appropriate time" in the appeal.

Phigenix submitted declarations it said showed that its licensing efforts have been hindered by ImmunoGen's patent, but the Federal Circuit said they were insufficient to establish standing.

Phigenix describes itself as a for-profit medical research company focused on cancer drugs and claims that while it does not make any products, it holds a patent that covers Genentech's Kadcycla. It challenged the ImmunoGen patent on the drug in an inter partes review, maintaining that the claimed invention is invalid as obvious, but the PTAB rejected that argument.

The Federal Circuit noted that on appeal, Phigenix did not contend that it faces a risk of infringing ImmunoGen's patent, but instead said that it suffered an injury that gives it standing because the the patent increases competition between the two companies.

Specifically, it said that ImmunoGen receives millions of dollars in licensing revenue for the patent, and some of that revenue would go to Phigenix if the patent were invalidated. It submitted declarations it said supported that claim, but the Federal Circuit said they did not include any facts that demonstrate an injury.

The court said that while it is possible that Phigenix's revenues would increase if it had licensed its patents to the same parties to which ImmunoGen has licensed its own patent, but "there is simply no allegation here" that Phigenix has ever licensed its patent to anyone, much less to those who have licensed ImmunoGen's patent.

"The conclusory statements ... as to the hypothetical licensing injury therefore do not satisfy the requirements" for standing, the court said.

The Federal Circuit reached a similar decision in 2014 when it found that a consumer group lacked standing to appeal a PTAB decision on a patent it had challenged in a re-examination, a different type of proceeding.

Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC, an attorney for ImmunoGen, said the company was pleased with the court's ruling, which she said applied the reasoning of the 2014 decision in the context of America Invents Act cases.

"This case will be important for petitioners going forward, as they consider whether to bring cases at the PTAB and whether they will have a right to appeal," she said.

Since the PTAB has no standing requirement to file a petition, the issue will arise for the first time in an appeal, and petitioners will need to think ahead.

"Anyone can bring an inter partes review at the administrative level, but not everyone can appeal," said Eric Steffe of Sterne Kessler, who also represented ImmunoGen.

An attorney for Phigenix could not immediately be reached for comment Monday.

Judges Timothy Dyk, Evan Wallach and Todd Hughes sat on the panel for the Federal Circuit.

The patent-in-suit is U.S. Patent Number 8,337,856.

Phigenix is represented by Gregory Porter, Robert Gutkin, Ping Wang and Michael Ye of Andrews Kurth Kenyon LLP.

ImmunoGen is represented by Eldora Ellison, Olga Partington, Pauline Pelletier, Byron Pickard and Eric Steffe of Sterne Kessler Goldstein & Fox PLLC.

The case is Phigenix Inc. v. ImmunoGen Inc., case number 2016-1544, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Kelly Duncan.

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