

<u>PHIGENIX</u>, INC. v. IMMUNOGEN, INC., Appeal No. 2016-1544 (Fed. Cir. January 9, 2017) (Dyk, <u>Wallach</u> and Hughes). Appealed from the Patent Trial and Appeal Board in IPR2014-00676.

Background:

Phigenix sought *inter partes* review of ImmunoGen's patent ('856 patent) alleging that the '856 patent was obvious in view of various prior art references. Phigenix owns a patent ('534 patent) related to an allegedly similar method of treating cancer.

The Board instituted *inter partes* review, and in a final written decision, the Board found the claims of the '856 patent to be nonobvious in view of the asserted prior art references. Phigenix appealed.

Issue/Holding:

Does Phigenix have Article III standing in the Federal Circuit to appeal the final written decision by the Board? - No, appeal dismissed.

Discussion:

The Federal Circuit held that Phigenix does not have standing to appeal the Board's decision because Phigenix did not present sufficient evidence to show that Phigenix suffered an injury in fact. The Federal Circuit, citing Supreme Court precedent, explained that an appellant must allege harm that is either actual or imminent in order to constitute an injury in fact.

For the first time, the Federal Circuit set forth the legal standard for demonstrating standing in an appeal from a final agency action. The Federal Circuit adopted the standard of the D.C. Circuit, which is based on *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). The Federal Circuit established that a party seeking review of an administrative action must identify sufficient evidence already of record, or submit additional evidence (i.e., affidavits and declarations), to demonstrate that the party has Article III standing at the earliest appropriate opportunity in the proceeding.

The Federal Circuit then turned to the evidence submitted by Phigenix and the facts alleged by Phigenix to show an injury in fact. Phigenix asserted that it had suffered an actual economic injury because the '856 patent increased competition in the market between Phigenix and ImmunoGen. Phigenix asserted that the existence of the '856 patent encumbered Phigenix's licensing efforts. However, the Federal Circuit held that Phigenix's evidence was insufficient to show that Phigenix has suffered an injury in fact. The Federal Circuit stated "there is simply no allegation here that Phigenix has ever licensed the '534 patent to anyone, much less that it licensed the '534 patent to entities that have obtained licenses to the ImmunoGen '856 patent." Thus, the Federal Circuit held that Phigenix failed to demonstrate an injury in fact sufficient to establish Article III standing because the evidence of record did not support an actual or imminent harm suffered by Phigenix due to the Board's upholding of the patentability of the '856 patent.

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