

Federal Circuit Dismisses IPR Appeal for Lack of Standing

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In *Phigenix v. ImmunoGen*, Appeal No. 16-1544 (Fed. Cir. Jan. 9, 2017), a precedential decision, the Federal Circuit found that the petitioner lacked standing to appeal the Patent Trial and Appeal Board's (PTAB) final written decision in an *inter partes* review proceeding. In its decision, the Federal Circuit indicated that it was setting forth, for the first time in its history, a legal standard for demonstrating standing in an appeal from a final agency action. This case is of importance to both patent owners and petitioners involved in PTAB proceedings, because not all parties who can challenge patents at the PTAB will have the right to appeal to the Federal Circuit.

The proceeding involved ImmunoGen's patent covering the cancer drug Kadcyla®. The PTAB found all claims of the patent nonobvious and, according to the Federal Circuit, Phigenix had not offered sufficient proof of an actual or imminent injury in fact, and therefore lacked standing to appeal.

The Legal Requirements for Demonstrating Standing in Appeal from an Agency Decision

In articulating the standing requirements, the Court explained that, though a statute may provide an appellant with a right to appeal an agency decision, a party "may lack 'constitutional standing' to sue in federal court." The opinion establishes that: (i) an appellant has the burden of production to establish standing; (ii) an appellant must use evidence to support its position; and (iii) an appellant must produce this evidence at "the first appropriate time" in the appeal. To have standing, an appellant "must have (1) suffered injury in fact, (2) that is fairly traceable to the challenged conduct of the appellee, (3) that is likely to be redressed by a favorable judicial decision." And although all the normal standards for redressability and immediacy need not be met in the context of an IPR/PGR appeal, "[a]n appellant's obligation to establish an injury in fact remains firm." The requirement for injury in fact requires that an injury is "both concrete and particularized—the harm must 'actually exist' or appear 'imminent,' and must affect an appellant 'in a personal and individual way.'"

The legal standard established by the Court involves three considerations. First, an appellant has a

burden of production—introducing enough evidence of a suffered injury. In this regard, an appellant's burden of production is “the same as that of a plaintiff moving for a summary judgment in the district court.”

Second, to meet its burden of production, an appellant must put forth evidence “to the extent necessary to explain and substantiate its entitlement to judicial review.” This is especially relevant in situations where standing is not “self-evident”—self-evident standing would arise when an appellant “is an object of the action (or forgone action) at issue.” Evidence of standing may include “arguments and any affidavits or other evidence.”

Third, the Court established the time for when an appellant should produce the evidence of standing: any evidence should be produced “at the first appropriate time.” Such time may be in response to a motion to dismiss, or in the opening brief, if the evidence was not already developed in the record below. Importantly, the Court made it clear that it is not necessary to establish Article III standing during an IPR or PGR itself; the evidence of standing can be introduced for the first time on appeal.

The Petitioner's Evidence was Insufficient to Demonstrate Standing

Under the standard established by the Court, Phigenix “has not demonstrated injury in fact.” Phigenix is a “for-profit discovery stage” research company that “does not manufacture any products” and that does not plan “to take any action that would implicate the patent” at issue. Phigenix alleged that the challenged patent increased competition between Phigenix and ImmunoGen and that the existence of ImmunoGen's patent “encumbered Phigenix's licensing efforts.” According to Phigenix, “increased competition represents a cognizable Article III injury.” In support, Phigenix submitted two declarations and a letter from an attorney to ImmunoGen regarding alleged concerns over the validity of ImmunoGen's patent.

The Court found that Phigenix failed to substantiate its allegations with sufficient evidence. Specifically, the Court found no evidence that Phigenix ever licensed its patent to anyone. According to the Court, Phigenix's evidence contained only “conclusory statements” regarding “the hypothetical licensing injury”—insufficient to establish injury in fact.

The Estoppel Provision Does Not Suffice as an Injury in Fact

If the PTAB issues a final decision on a patent claim in an IPR, a petitioner is statutorily barred from requesting or maintaining any proceeding before the Patent Office, US International Trade Commission, or a federal district court with respect to that claim on a ground that the petitioner “raised or reasonably could have raised” during that *inter partes* review. Phigenix argued that this estoppel effect “adversely impacts Phigenix’s ability to provide a contractual warranty,” and thus constitutes an injury in fact. The Court found that because Phigenix was “not engaged in any activity that would give rise to a possible infringement suit,” the estoppel provision “does not constitute an injury in fact.”

What is the impact of the decision?

In light of this decision, potential petitioners will carefully consider their ability to appeal when contemplating whether — or when — to challenge a patent at the PTAB. And though Article III standing need not be established to challenge a patent at the PTAB, a petitioner should be prepared to demonstrate such standing when seeking to invoke the jurisdiction of the Federal Circuit. Though the Federal Circuit expressly articulated a standard for establishing standing, parties are likely to test how the court will apply the newly-articulated standard to a given factual scenario when a petitioner appeals a decision of the PTAB — particularly in cases where the petitioner is a hedge fund, public interest group, or some other non-practicing entity.

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