Federal Circuit clarifies injury-in-fact requirement for standing after PTAB proceedings

BY KENNETH MATUSZEWSKI AND ISAAC RABICOFF

Recently, the Federal Circuit clarified the injury in fact element necessary to show standing under Article III in *Phigenix v. ImmunoGen.* No. 2016-1544, 2017 U.S. App. LEXIS 323 (Fed. Cir. 2017).

Generally, courts have "an obligation to assure [themselves] of litigants' standing under Article III . . . including when a party appeals from a final agency action." In order to bring a case in federal court, parties must meet the three elements for standing: 1) the [appellant] suffered an injury in fact, 2) that is fairly traceable to the challenged conduct of the [appellee] and 3) that is likely to be redressed by a favorable judicial decision. Specifically, the first element, injury in fact, requires an appellant to have an injury that actually exists or will imminently cause harm.

While Article III standing is not necessary to appear before an administrative agency such as the Patent Trial and Appeal Board ("PTAB") under 35 U.S.C. § 6(a), appellants must have an injury in fact when seeking review of an agency's final action in federal court.

Phigenix, Inc., a "for-profit discovery stage biotechnology, pharmaceutical, and biomedical research company" focuses "on the use of novel molecular therapeutics" to treat cancer, but does not manufacture any products. At the time of the suit, Phigenix was developing a large IP portfolio.

In order to protect the portfolio's development, Phigenix filed an Inter Partes Review ("IPR") for patent 8,337,856 ("the '856 patent") under 35 U.S.C. § 311, which ImmunoGen owned as an assignee. When the PTAB found the '856 patent was not obvious in a final written decision, Phigenix appealed the PTAB's decision at the Federal Circuit.

However, the Federal Circuit held Phigenix was unable to appeal the PTAB's final written decision, because it did not have standing under Article III. Specifically, Phigenix did not show it suffered an injury in fact from the IPR decision.

The Federal Circuit first opined that while the court had not yet established the legal test for determining standing in an appeal from an administrative action, the standard must identify: 1) the burden of production; 2) the evidence to meet that burden of production; and 3) when an appellant must produce that evidence.

The Federal Circuit then held an appellant's burden of production to show standing is "the same as that of a plaintiff moving for summary judgment in the district court," a standard for summary judgment also used in the 6th, 7th, 8th, 10th and D.C. Circuits. As a result, burden of production used in summary judgments applies in cases where parties desire appellate review of a final agency action. Appellants can meet this burden by using evidence in the record or affidavits.

Phigenix argued it suffered economic injury sufficient for standing because the '856 patent increased competition between it and ImmunoGen. Phigenix did not discuss whether it was at risk of infringing the '856 patent, was an actual or prospective licensee of the '856 patent or that it otherwise planned to take any actions with the '856 patent. It also did not provide any evidence from the PTAB record.

While Phigenix included a letter illustrating its concerns over the patent's validity, and its beliefs that "it ha[d] a strong patent portfolio," the letter did not discuss any issues of fact admissible as evidence. Therefore, Phigenix did not produce enough evidence to establish standing, because it did not meet the burden of production at summary judgment.

The Federal Circuit acknowledged that violating a procedural right granted by statute would be sufficient to constitute an injury in fact in some circumstances. However, Phigenix was allowed to appeal the PTAB's final written decision in the IPR to the Federal Circuit. As a result, just

because Phigenix exercised its right to appeal, it did not necessarily establish it had standing under Article III.

Finally, Phigenix argued it had an injury in fact because "the estoppel effect of the [PTAB]'s decision adversely impact[ed] Phigenix's ability to provide a contractual warranty," and violated 35 U.S.C. § 315(e). The Federal Circuit then ruled estoppel provisions are not injuries in fact when the appellant does not engage in any activity that could give rise to a possible infringement suit. Specifically, developing an IP portfolio did not necessarily mean Phigenix would try to infringe the patent.

As a result, the Federal Circuit held Phigenix did not have standing to bring the case to the Federal Circuit, the only court that can hear appeals from the PTAB under 35 U.S.C. § 141(a), and dismissed the case. Thus, while standing is not required to institute an IPR, parties might find it prudent to determine whether they would have standing in federal court before filing an IPR to avoid the problems Phigenix faced.



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