

**United States Court of Appeals
for the Federal Circuit**

PHIGENIX, INC.,
Appellant

v.

IMMUNOGEN, INC.,
Appellee

2016-1544

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2014-00676.

Decided: January 9, 2017

GREGORY LAWRENCE PORTER, Andrews Kurth Kenyon LLP, Houston, TX, argued for appellant. Also represented by ROBERT ALAN GUTKIN, PING WANG, MICHAEL YE, Washington, DC.

ELDORA ELLISON, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for appellee. Also represented by OLGA A. PARTINGTON, PAULINE PELLETIER, BYRON LEROY PICKARD, ERIC K. STEFFE.

Before DYK, WALLACH, and HUGHES, *Circuit Judges*.

WALLACH, *Circuit Judge*.

Appellant Phigenix, Inc. (“Phigenix”) sought inter partes review of U.S. Patent No. 8,337,856 (“the ’856 patent”), alleging that claims 1–8 (“the Asserted Claims”) of the subject patent are unpatentable as obvious over various prior art references. In its final written decision, the U.S. Patent and Trademark Office’s (“USPTO”) Patent Trial and Appeal Board (“PTAB”) found the Asserted Claims nonobvious. *See generally Phigenix, Inc. v. ImmunoGen, Inc.*, No. IPR2014-00676, 2015 WL 6550500 (P.T.A.B. Oct. 27, 2015).

Phigenix appeals. We possess subject matter jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (2012). 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. We dismiss.

BACKGROUND

The ’856 patent generally relates to “huMab4D5 ANTI-ErbB2 antibody-maytansinoid conjugates.” ’856 patent, Title. The claimed methods of treatment purport to combat a variety of cancers. *See id.* col. 4 ll. 26–42.

The subject dispute involves three principal parties, each of whom allege to have some relation to the ’856 patent. The first party, Appellee ImmunoGen, Inc. (“ImmunoGen”), is the assignee of the ’856 patent. ImmunoGen provided the second party, Genentech Inc. (“Genentech”), with a “worldwide exclusive license” to the subject patent, which Genentech uses to produce the drug Kadcyła®™ (“Kadcyla”). *Phigenix, Inc. v. ImmunoGen, Inc.*, No. 2016-1544, Docket No. 23 at Ex. A, ¶ 3 (Fed. Cir. Mar. 4, 2016) (ImmunoGen’s Mot. to Dismiss (“ImmunoGen’s MTD”)); *see id.* at Ex. A, ¶ 2. The third party, Phigenix, describes itself “as a for-profit discovery stage biotechnology, pharmaceutical, and biomedical research company” that focuses “on the use of novel molecular

therapeutics” designed to fight cancer. *Phigenix, Inc. v. ImmunoGen, Inc.*, No. 2016-1544, Docket No. 26 at Ex. 1, ¶ 4 (Fed. Cir. Mar. 14, 2016) (Phigenix’s Resp. to ImmunoGen’s MTD (“Phigenix’s Resp. to MTD”)). Phigenix does not manufacture any products, but purportedly “has developed, and is developing, an extensive intellectual property portfolio” that includes U.S. Patent No. 8,080,534 (“the ’534 patent”). *Id.* at Ex. 1, ¶ 5; *see id.* at Ex. 1, ¶ 7. Phigenix alleges that the ’534 patent covers Genentech’s “activities relating to Kadcyla[]” and, thus, the subject matter claimed in the ’856 patent. *Id.* at Ex. 1, ¶ 7; *see id.* at Ex. 1, ¶¶ 8–9, and Ex. 2, ¶ 14. Phigenix alleges that it “was forced” to bring litigation in various fora when Genentech refused its offer to license the ’534 patent. *Id.* at Ex. 1, ¶ 8.

In that vein, and “[t]o further its commercialization efforts with respect to its patent portfolio,” Phigenix sought inter partes review of the Asserted Claims of the ’856 patent. *Id.* at Ex. 1, ¶ 10. When the PTAB found the Asserted Claims nonobvious, Phigenix sought further review in this court.

DISCUSSION

I. Phigenix Lacks Article III Standing

Before the parties fully briefed the subject appeal, ImmunoGen filed a motion to dismiss, asserting that Phigenix lacked standing to appeal the PTAB’s Final Written Decision. *See generally* ImmunoGen’s MTD. Phigenix opposed. *See generally* Phigenix’s Resp. to MTD. A single judge of this court denied the Motion, “deem[ing] it the better course for the parties to address the standing issue in their briefs.” *Phigenix, Inc. v. ImmunoGen, Inc.*, No. 2016-1544 (Fed. Cir. Apr. 20, 2016) (order denying ImmunoGen’s MTD).

In its response brief, ImmunoGen argues anew that Phigenix lacks standing, Appellee’s Br. 29–37, and Phige-

nix again opposes, Appellant’s Br. 24–25 (incorporating the arguments made in Phigenix’s Resp. to MTD); Appellant’s Reply 3–16. “We have an obligation to assure ourselves of litigants’ standing under Article III” of the Constitution, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 340 (2006) (internal quotation marks and citation omitted), including when a party appeals from a final agency action, see *Massachusetts v. EPA*, 549 U.S. 497, 505–06, 516–26 (2007). As the party seeking judicial review, Phigenix bears the burden of establishing that it has standing. See *DaimlerChrysler*, 547 U.S. at 342.

A. General Article III Standing Requirements

“Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy” required by Article III. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *Hollingsworth v. Perry*, 133 S. Ct. 2652, 2661 (2013) (explaining that Article III discusses the powers granted to the Judicial Branch and, inter alia, “confines the judicial power of federal courts to deciding actual ‘Cases’ or ‘Controversies’” (quoting U.S. Const. art. III, § 2)). “[T]he irreducible constitutional minimum of standing” consists of “three elements.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). An appellant “must have (1) suffered an 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.”¹ *Spokeo*, 136 S. Ct. at 1547 (citations omitted).

¹ We recite the standing framework using the designations “appellant” and “appellee,” rather than “plaintiff” and “defendant,” because we are the court of first instance in an appeal challenging the PTAB’s final written decision in an inter parties review. 35 U.S.C. § 141(c) (2012) (“A party to an inter partes review . . . who is dissatisfied with the final written decision of the

As to the first element, “the injury-in-fact requirement requires [an appellant] to allege an injury that is both concrete *and* particularized.” *Id.* at 1545 (internal quotation marks and citation omitted). To constitute a “concrete” injury, the harm must “actually exist,” *id.* at 1548 (citation omitted), or appear “imminent,” *Lujan*, 504 U.S. at 560 (internal quotation marks and citation omitted)—a “conjectural or hypothetical” injury will not suffice, *id.* (internal quotation marks and citation omitted). And an injury is “particularized” if it affects an appellant “in a personal and individual way.” *Spokeo*, 136 S. Ct. at 1548 (internal quotation marks and citation omitted).

“[A]lthough Article III standing is not necessarily a requirement to appear before an administrative agency,” *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014) (citation omitted), an appellant must nevertheless supply the requisite proof of an injury in fact when it seeks review of an agency’s final action in a federal court,² *see Massachusetts*, 549 U.S. at 517 (explaining that, when a party appeals from a final agency action, it must demonstrate that it suffers an injury “that is either actual or imminent” (quoting *Lujan*, 504 U.S. at 560–61)). Indeed, the Supreme Court has recognized that not every party will have Article III standing in an appeal from a PTAB final written decision. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016) (explaining that, although a party that

[PTAB] . . . may appeal the [PTAB]’s decision only to the . . . Federal Circuit.”).

² An appellant’s obligation to establish an injury in fact remains firm even though it need not “meet[] all the normal standards for redressability and immediacy” when, as here, a statute provides the appellant with a right to appeal. *Massachusetts*, 549 U.S. at 517–18 (quoting *Lujan*, 504 U.S. at 572 n.7).

initiated an inter partes review “need not have a concrete stake in the outcome,” it “may lack constitutional standing” to sue in federal court).

B. The Legal Requirements to Demonstrate Standing in an Appeal from a Final Agency Action

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. This standard must identify the burden of production;³ the evidence an appellant must produce to meet that burden; and when an appellant must produce that evidence. We discuss each item in turn.

As to the burden of production, the Supreme Court has held that each element is “an indispensable part of” an appellant’s case and “must be supported in the same way as any other matter on which the [appellant] bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Lujan*, 504 U.S. at 561. Interpreting *Lujan*, the D.C. Circuit has held that an appellant’s burden of production is “the same as that of a plaintiff moving for summary judgment in the district court.” *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002) (citation omitted). At least four of our sister circuits have adopted the D.C. Circuit’s standard, *see Sierra Club v. EPA*, 793 F.3d 656, 662–663 (6th Cir. 2015), *cert. denied sub nom.*, *Ohio v. Sierra Club*, 136 S. Ct. 1491 (2016); *N. Laramie Range All. v. FERC*, 733 F.3d 1030, 1034 (10th Cir. 2013); *Iowa*

³ “Burden of production” means “[a] party’s duty to introduce enough evidence on an issue to have the issue decided by the fact-finder, rather than decided against the party in a peremptory ruling such as a summary judgment or a directed verdict.” *Burden of Production*, Black’s Law Dictionary (10th ed. 2014).

League of Cities v. EPA, 711 F.3d 844, 869–70 (8th Cir. 2013); *Citizens Against Ruining the Env't v. EPA*, 535 F.3d 670, 675 (7th Cir. 2008), and two others appear to have followed it, see *Ass'n of Pub. Agency Customers v. Bonneville Power Admin.*, 733 F.3d 939, 971 n.7 (9th Cir. 2013) (Alarcón, J., dissenting) (explaining that the Ninth Circuit has appeared to follow, but not expressly adopted, the burden of production standard articulated in *Sierra Club*, 292 F.3d 895); *Manufactured Hous. Inst. v. EPA*, 467 F.3d 391, 398 (4th Cir. 2006) (similar).⁴ Our review of *Lujan* and the Supreme Court's subsequent decisions leads us to conclude that the summary judgment burden of production applies in cases where an appellant seeks review of a final agency action and its standing comes into doubt. See *Lujan*, 504 U.S. at 561 (explaining that a party challenging government action may demonstrate its standing, inter alia, “at the summary judgment stage”); see also *Massachusetts*, 549 U.S. at 521–23 (relying upon evidence typically produced at the summary judgment stage (i.e., affidavits and declarations) to find that a party possessed standing in an appeal from a final agency action).

Having established the relevant burden of production, we turn to what evidence will meet the burden. The D.C. Circuit has held that, in some cases, an appellant's “standing to seek review of administrative action is self-evident; no evidence outside the administrative record is necessary for the court to be sure of it.” *Sierra Club*, 292 F.3d at 899–900. Self-evident standing typically arises when an appellant “is ‘an object of the action (or forgone

⁴ The First, Second, Third, Fifth, and Eleventh Circuits do not appear to have addressed the precise issue before us.

action) at issue.”⁵ *Id.* at 900 (quoting *Lujan*, 504 U.S. at 561–62). “When the [appellant]’s standing is not self-evident, however, the [appellant] must supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review.” *Id.* In so doing, an appellant may submit “arguments and any affidavits or other evidence” to demonstrate its standing. *Id.* Taken together, an appellant “must either identify . . . record evidence sufficient to support its standing to seek review or, if there is none because standing was not an issue before the agency, submit additional evidence to the court of appeals,” such as “by affidavit or other evidence.” *Id.* at 899 (internal quotation marks and citation omitted).

Finally, we must determine when an appellant should produce the evidence establishing its standing. Because standing involves threshold questions over a court’s authority to hear a dispute, see *Massachusetts*, 549 U.S. at 505, an appellant must identify the relevant evidence demonstrating its standing “at the first appropriate” time, whether in response to a motion to dismiss or in the opening brief, *Sierra Club*, 292 F.3d at 900; see *id.* at 901. Imposing on an appellant the dual obligations of producing the evidence and producing the evidence early in the litigation comports with the reality that such evidence is “necessarily peculiar to” the appellant and “ordinarily within its possession.” *Id.* at 901. Thus, if there is no record evidence to support standing, the appellant must produce such evidence at the appellate level at the earliest possible opportunity.

⁵ “[W]hen the [appellant] is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish.” *Lujan*, 504 U.S. at 562 (internal quotation marks and citations omitted).

C. Phigenix Has Not Demonstrated Injury in Fact

Having identified the operative standards, we turn to the question of Phigenix's standing. Phigenix has argued its standing in several submissions, *see generally* Phigenix's Resp. to MTD; Appellant's Br.; Appellant's Reply, as well as put into evidence two declarations that purportedly demonstrate its standing, *see* Phigenix's Resp. to MTD at Ex. 1 ("Donald Decl.") and Ex. 2 ("Gold Decl."). In these documents, Phigenix does not contend that it faces risk of infringing the '856 patent, that it is an actual or prospective licensee of the patent, or that it otherwise plans to take any action that would implicate the patent. *See generally* Phigenix's Resp. to MTD; Appellant's Br.; Appellant's Reply. Instead, Phigenix asserts that it has suffered an actual economic injury because the '856 patent increases competition between itself and ImmunoGen, *see* Phigenix's Resp. to MTD at 6, and "[i]ncreased competition represents a cognizable Article III injury," *id.* (quoting *Liquid Carbonic Indus. Corp. v. FERC*, 29 F.3d 697, 701 (D.C. Cir. 1994)).

Phigenix argues that "[t]he existence of ImmunoGen's '856 patent has . . . encumber[ed] Phigenix's licensing efforts while ImmunoGen receives millions of dollars in licensing revenue." *Id.* at 9; *see id.* at 9–10 (citing Gold Decl. at ¶¶ 10, 15). Phigenix contends "[t]he most reasonable and commonsense conclusion is that at least a portion of that licensing revenue would inure to Phigenix if the '856 patent were invalidated." Appellant's Reply 9–10. Phigenix does not substantiate these arguments with record evidence developed before the PTAB. *See generally* Phigenix's Resp. to MTD; Appellant's Br.; Appellant's Reply. Instead, Phigenix relies principally upon the declarations accompanying its response to ImmunoGen's Motion to Dismiss and another non-record document.

Rule 56(c)(4) explains that a "declaration used to support . . . a motion must be made on personal knowledge,

set out *facts* that would be admissible in evidence, and show that the . . . declarant is competent to testify on the matters stated.” Fed. R. Civ. P. 56(c)(4) (emphasis added). A “conclusion[] of law” in a declaration “cannot be utilized [i]n a summary-judgment motion.” 10B Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 2738 (4th ed. 2016) (internal quotation marks and footnotes omitted); *accord F.R.C. Int’l, Inc. v. United States*, 278 F.3d 641, 643 (6th Cir. 2002); *Schubert v. Nissan Motor Corp. in U.S.A.*, 148 F.3d 25, 30–31 (1st Cir. 1998); *Orthopedic & Sports Injury Clinic v. Wang Labs., Inc.*, 922 F.2d 220, 224 (5th Cir. 1991); *Barfield v. Orange Cty.*, 911 F.2d 644, 650 (11th Cir. 1990); *Toro Co. v. Krouse, Kern & Co.*, 827 F.2d 155, 162 n.3 (7th Cir. 1987).

Phigenix’s documents do not have such supporting facts. As stated above, Phigenix relies upon the Gold Declaration to argue that “[t]he existence of ImmunoGen’s ’856 patent has . . . encumber[ed] Phigenix’s licensing efforts.” Phigenix’s Resp. to MTD at 9; *see id.* at 9–10 (citing Gold Decl. at ¶¶ 10, 15). Phigenix also alleges that a letter highlighting concerns over the ’856 patent’s validity that its attorney sent to ImmunoGen “underscores the actual, concrete controversy” between the parties. Appellant’s Br. 25. In that letter, counsel stated that Phigenix “believes that it has a strong patent portfolio” and “believes” that the ’856 patent is invalid. J.A. 6446.

The Gold Declaration and the attorney letter are insufficient to demonstrate injury in fact. It is possible that, if Phigenix had licensed the ’534 patent to the same parties to which ImmunoGen had licensed the ’856 patent, the invalidation of the ’856 patent might have increased Phigenix’s revenues. However, 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. The conclusory statements in

the Gold Declaration and the letter as to the hypothetical licensing injury therefore do not satisfy the requirements of Rule 56(c)(4).⁶ *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888 (1990) (explaining that “[t]he object” of Rule 56 “is not to replace conclusory allegations of the complaint or answer with conclusory allegations of an affidavit”).

Phigenix’s remaining arguments do not necessitate a different conclusion. Phigenix contends that it has suffered an injury in fact because 35 U.S.C. § 141(c) “provides a statutory basis for appeal,” Phigenix’s Resp. to MTD at 16, and *Spokeo* recognizes that “[t]he violation of a procedural right granted by statute can be sufficient in

⁶ Several aspects of the Declarations submitted by Phigenix also fail to lay the requisite foundation to be “admissible in evidence,” as Rule 56(c)(4) requires. *See* 10B Charles Alan Wright & Arthur R. Miller, *Fed. Prac. & Proc.* § 2738 (4th ed. 2016) (explaining that “the rules of evidence and their exceptions determine what allegations the affidavit may contain” (footnote omitted)); *see also* Fed. R. Evid. 901(a) (“To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is.”). For example, Dr. Carlton D. Donald testified that “Phigenix and Genentech had multiple discussions through . . . telephone conversations concerning the Phigenix technology and its patent portfolio,” Donald Decl. at ¶ 8; however, Dr. Donald does not establish that (1) a particular number was dialed; (2) the number dialed was “assigned at the time” to Genentech; or (3) “the call related to business reasonably transacted over the telephone,” Fed. R. Evid. 901(b)(6).

some circumstances to constitute an injury in fact,”⁷ Appellant’s Reply 16 (emphasis added) (quoting 136 S. Ct. at 1549). In relevant part, § 141(c) provides that “[a] party to an inter partes review . . . who is dissatisfied with the final written decision of the [PTAB] . . . may appeal the [PTAB]’s decision” to this court. Phigenix cannot base its injury in fact upon a violation of § 141(c) because it has been permitted to file its appeal, and the exercise of its right to appeal does not necessarily establish that it possesses Article III standing. *See Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997) (“Congress cannot erase Article III’s standing requirements by statutorily granting the right to sue to [an appellant] who could not otherwise have standing.” (citation omitted)). As the Supreme Court has observed, statutorily “broadening the categories of injury that may be alleged in support of standing is a different matter from abandoning the requirement that the party seeking review must himself have suffered an injury.” *Sierra Club v. Morton*, 405 U.S. 727, 738 (1972); *accord Massachusetts*, 549 U.S. at 516–17 (discussing the need for injury in fact to pursue appeal from a final agency action); *Lujan*, 504 U.S. at 578 (same).

Finally, Phigenix asserts an injury in fact based on 35 U.S.C. § 315(e), arguing that “the estoppel effect of the [PTAB]’s decision adversely impacts Phigenix’s ability to provide a contractual warranty.” Appellant’s Reply 11 (capitalization modified). If the PTAB issues a final written decision in an inter partes review on a patent

⁷ To the extent Phigenix alleges that *Spokeo* overruled the Supreme Court’s prior decisions on standing, that argument ignores governing law. *See Hohn v. United States*, 524 U.S. 236, 252–53 (1998) (“Our decisions remain binding precedent until we see fit to reconsider them, regardless of whether subsequent cases have raised doubts about their continuing vitality.” (citation omitted)).

claim, a petitioner “may not request or maintain a proceeding before” the USPTO, the U.S. International Trade Commission, or a federal district court “with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.” 35 U.S.C. § 315(e)(1); *see id.* § 315(e)(2). In *Consumer Watchdog*, we explained that a similar estoppel provision “do[es] not constitute an injury in fact” when, as here, the appellant “is not engaged in any activity that would give rise to a possible infringement suit.” 753 F.3d at 1262 (citation omitted). We see no reason to reach a different conclusion on the facts before us.

CONCLUSION

Because Phigenix has not substantiated its alleged injury in fact, it lacks standing to appeal the PTAB’s Final Written Decision affirming the patentability of the Asserted Claims of the ’856 patent. We have considered Phigenix’s remaining arguments to the contrary and find them unpersuasive. Accordingly, Phigenix’s appeal is

DISMISSED