United States Court of Appeals for the Federal Circuit

ALTAIRE PHARMACEUTICALS, INC.,
Appellant

v.

PARAGON BIOTECK, INC.,
Appellee

2017-1487

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2015-00011.

Decided: May 2, 2018

CRAIG E. COUNTRYMAN, Fish & Richardson, PC, San Diego, CA, argued for appellant. Also represented by OLIVER RICHARDS; CHARLES W. SABER, DIPU A. DOSHI, JONATHAN W.S. ENGLAND, MARK J. THRONSON, Blank Rome LLP, Washington, DC.

RICHARD TORCZON, Wilson, Sonsini, Goodrich & Rosati, PC, Washington, DC, argued for appellee. Also represented by MICHAEL T. ROSATO, ANDREW SWANSON BROWN, SONJA ROCHELLE GERRARD, STEVEN WILLIAM PARMELEE, Seattle, WA; DOUGLAS H. CARSTEN, San Diego, CA.

Before O'MALLEY, SCHALL, and WALLACH, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* WALLACH.

Dissenting opinion filed by *Circuit Judge* SCHALL.

WALLACH, *Circuit Judge*.

Appellant Altaire Pharmaceuticals, Inc. ("Altaire") sought post-grant review of claims 1–13 ("the Asserted Claims") of Appellee Paragon Bioteck, Inc.'s ("Paragon") U.S. Patent No. 8,859,623 ("the '623 patent"). The U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") issued a final written decision determining that Altaire failed to prove that the Asserted Claims were unpatentable for obviousness over two production lots of Altaire's phenylephrine hydrochloride ophthalmic solution products, Lots #11578 and #11581,[1] which are used to dilate patients' pupils. *See Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, No. PGR2015-00011 (P.T.A.B. Nov. 14, 2016) (J.A. 1–21).

Altaire appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (2012). We reverse-in-part, vacate-in-part, and remand.

BACKGROUND

I. The Relevant Facts

Phenylephrine contains a chiral center with two enantiomers known as R- and S-phenylephrine hydrochloride. J.A. 2; *see* J.A. 1150. The R-phenylephrine hydrochloride,

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[1] Lots #11581 and #11582 are the same formulation. J.A. 738. Altaire relied on testing performed on Lot #11582 to support its assertion that the Asserted Claims would have been obvious over Lots #11578 and #11581. *See, e.g.*, J.A. 737–38.

but not the S-phenylephrine hydrochloride, is useful to dilate pupils. *See* '623 patent col. 6 ll. 21–30; *see also* J.A. 737. To determine the phenylephrine hydrochloride products' effectiveness, industry members measure the products' "chiral purity," which is the relative amount of each enantiomer expressed as a percentage. *See* '623 patent col. 1 ll. 15–20, col. 3 ll. 43–48; *see also* J.A. 750.

By 2000, Altaire was manufacturing R-phenylephrine hydrochloride products, including products containing 2.5% and 10% phenylephrine hydrochloride ophthalmic solution. J.A. 733. In 2011, Altaire and Paragon entered into an agreement to pursue U.S. Food and Drug Administration ("FDA") approval for Altaire's products. *See* J.A. 1909–13 ("the Agreement"). Pursuant to the Agreement, "Paragon shall be responsible for preparing and submitting the [new drug] applications [('NDAs')] in support of the products," and "Altaire will provide and bear the costs for the chemistry, manufacturing, and controls . . . in support of an NDA filing for the products." J.A. 1910 (capitalization modified).

Paragon submitted an NDA, and the FDA responded by recommending that Paragon, inter alia, "[c]onsider adding a chiral purity test to the d[r]ug product specification or provide a justification for not doing so." J.A. 773. In response, Altaire measured the optical rotation of Lot #11578, a 2.5% phenylephrine hydrochloride ophthalmic solution product, and Lot #11582, a 10% phenylephrine hydrochloride ophthalmic solution product, *see* J.A. 783–91; *see also* '623 patent col. 4 ll. 33–34 ("[I]t is known in the art chiral purity can be determined by optical rotation."). Altaire provided a summary of these optical rotation test results to Paragon, and Paragon submitted a supplementary NDA filing to the FDA, which approved Paragon's NDA in March 2013. J.A. 739; *see* J.A. 783–91. In addition to the optical rotation tests, Altaire conducted high performance liquid chromatography ("HPLC") test-

ing on Lots #11578 and #11582, which it internally refers to as "TMQC-247." J.A. 11, 802.

In June 2013, Paragon's counsel proposed an amendment to the Agreement "to address [a] new patent application filing . . . discussed with Altaire." J.A. 1840. Altaire responded that: "the formulation, processes[,] and controls applicable to the . . . product[s] were developed solely by [Altaire's Chief Executive Mr.] Al Sawaya and Altaire[] and are . . . the proprietary and confidential information of Altaire"; the Agreement "does not contemplate Paragon using such information to support a patent application"; and "any such patent application should identify either [Mr.] Al Sawaya or Altaire as the sole inventor." J.A. 1839. Although Paragon's counsel responded that they "look[ed] forward to further discussions," J.A. 1839, there is no indication in the record that Paragon's counsel responded to the substantive comments raised by Altaire.

In November 2013, Paragon filed a drug patent application that issued as the '623 patent. J.A. 22. Entitled "Methods and Compositions of Stable Phenylephrine Formulations," the '623 patent includes thirteen claims. '623 patent col. 12 l. 39–col. 13 l. 14. Independent claim 1 is illustrative and recites:

> A method of using an ophthalmic composition for pupil dilation, the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95% and an aqueous buffer, wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months, the method comprising:
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> > administering the composition into an eye of an individual in need thereof, wherein the composition is stored between -10 to 10 degree Celsius prior to administration, and wherein the composition comprises R-

> phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage.

Id. col. 12 ll. 39–50. Dependent claims 2–13 depend from independent claim 1, either directly or indirectly. *See id.* col. 12 l. 51–col. 13 l. 14.

In March 2014, while the application that led to the '623 patent was being prosecuted, Paragon requested "all the work [Altaire] ha[s] on chiral purity" for its annual report to the FDA. J.A. 1606. In response, Altaire sent Paragon a report purporting to confirm that Altaire's TMQC-247 methodology accurately measures relative quantities of R- or S-phenylephrine hydrochloride. J.A. 1602; *see* J.A. 1536–601, 1603–05.

In April 2015, Altaire filed a complaint against Paragon in the U.S. District Court for the Eastern District of New York ("Eastern District"), alleging that Paragon breached a nondisclosure clause of the Agreement between the parties, *see* Appellant's Br. viii; Appellee's Br. vii, and Paragon responded by alleging that Altaire materially breached the nondisclosure clause and seeking the right to terminate the Agreement, J.A. 1012, 1020; *see* J.A. 1911–12 (Non-Disclosure Clause). In April 2017, Altaire filed another complaint against Paragon in the Eastern District, seeking a declaratory judgment of invalidity of the '623 patent. *See* Appellant's Br. viii; Appellee's Br. vii, 22–23. At the time of argument, both of these actions were pending.

II. Procedural History

In May 2015, Altaire filed a petition for post-grant review of the '623 patent, arguing that the Asserted Claims would have been obvious over Lots #11578 and #11581, *see* J.A. 37–114, and attaching the supporting declaration

of Mr. Al Sawaya[2] ("First Al Sawaya Declaration"), *see* J.A. 732–61. As relevant here, Altaire contended that: the product labeling of Lots #11578 and #11581 instructed that the products should be stored between 2 and 8 degrees Celsius, *see* J.A. 50–52, 733–35, which is within the -10 to 10 degrees Celsius range required by the Asserted Claims, *see* '623 patent col. 12 l. 47; and the TMQC-247 test results demonstrated that Lots #11578 and #11581 remained at 99.99% chiral purity, *see* J.A. 65–69, 745–51, 796–99, 802–03, which exceeds the 95% chiral purity minimum of the Asserted Claims, *see* '623 patent col. 12 l. 50.

Paragon filed a preliminary response. *See* J.A. 804–47. As relevant here, Paragon argued that: Mr. Al Sawaya "is not an expert or even [a person having] ordinary skill in the art [('PHOSITA')], but rather, a fact witness," J.A. 824; *see* J.A. 824–26; and "the techniques upon which the petition relies—*i.e.*, (1) a [United States Pharmacopeia ('USP')] standard HPLC protocol" that does not measure relative quantities of R- or S-phenylephrine hydrochloride; and "(2) an optical rotation comparison—cannot reliably determine chiral purity," J.A. 818; *see* J.A. 818–24.

The PTAB determined that "it is more likely than not that [the Asserted Claims] of the '623 patent are unpatentable as obvious over Altaire's [p]roduct[s]" and instituted post-grant review. J.A. 1079; *see* J.A. 1061–81. In its patent owner response, Paragon, inter alia, reiterated its challenge to the First Al Sawaya Declaration, *see* J.A. 1112–15, and contended that the tests Altaire performed on Lots #11578 and #11581 do not satisfy the requirements of 37 C.F.R. § 42.65(b) (2016), *see* J.A. 1115–

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[2] While the record refers to the President of Altaire as both "Al Sawaya" and "Assad Sawaya," we refer to him as "Mr. Al Sawaya" for consistency.

22, which requires parties "rel[ying] on a technical test or data from such a test" to

> provide an affidavit explaining: (1) [w]hy the test or data is being used; (2) [h]ow the test was performed and the data was generated; (3) [h]ow the data is used to determine a value; (4) [h]ow the test is regarded in the relevant art; and (5) [a]ny other information necessary for the [PTAB] to evaluate the test and data.

37 C.F.R. § 42.65(b).

In its reply, Altaire included a second declaration of Mr. Al Sawaya ("Second Al Sawaya Declaration"), discussing his experience in the pharmaceutical industry. *See* J.A. 1418–25. Altaire contended that its TMQC-247 test differs from the standard HPLC test in the USP, *see* J.A. 1393–99, and provided additional information regarding how the TMQC-247 test is performed, *see* J.A. 1505–601, as well as evidence that this test data previously had been shared with Paragon during the FDA approval process, *see* J.A. 1602–06.[3] Finally, Altaire argued that Paragon previously acknowledged the validity of optical rotation test data by submitting them to the FDA and discussing optical rotation testing in the '623 patent. *See* J.A. 1390, 1401–02.

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[3] Altaire argued that, regardless of whether the USP standard HPLC separates R- and S-phenylephrine hydrochloride, Altaire developed the TMQC-247 testing method as a "proprietary HPLC procedure" to measure relative quantities of R- and S-phenylephrine hydrochloride. J.A. 11; *see* J.A. 1506. Altaire further contended that it validated that its TMQC-247 testing method satisfies the USP testing guidelines. J.A. 12–13; *see* J.A. 1539; *see also* J.A. 971–76.

In its Final Written Decision, the PTAB determined that Altaire had failed to prove by a preponderance of the evidence that the Asserted Claims would have been obvious. J.A. 20. In reaching this conclusion, the PTAB determined that Altaire failed to timely qualify Mr. Al Sawaya as an expert, *see* J.A. 7–9, the TMQC-247 test data were entitled to no weight, *see* J.A. 10–17, and the optical rotation test data were unpersuasive, *see* J.A. 17–20.

DISCUSSION

I. Altaire Has Article III Standing

In its opening brief,[4] Altaire argued that it has Article III standing "because it faces an imminent risk of suit on the '623 patent and it is suffering a concrete reputational injury based on Paragon's misappropriation of Altaire's invention." Appellant's Br. 47; *see id.* at 47–52; Reply Br. 28. Paragon opposed, arguing that Altaire lacks standing "because [Altaire] is not now engaging in infringing activities and any future plans it may have to engage in infringing activities are, at most, contingent" and that "Altaire has suffered no reputational injury for failing to be named as an inventor, and . . . , even if had suffered such injury, it could not be remedied by post-grant review

[4] Before the parties fully briefed this appeal, Paragon filed a motion to dismiss, asserting that Altaire lacked Article III standing to appeal the PTAB's Final Written Decision. *See* Paragon's Mot. to Dismiss 1, ECF No. 16. Altaire opposed, *see* Altaire's Opp'n to Paragon's Mot. to Dismiss 1, ECF No. 25, and Paragon replied, *see* Paragon's Reply in Supp. of Its Mot. to Dismiss 1, ECF No. 29. A single judge of this court "deem[ed] it the better course to deny the motion and for the parties to address standing in their briefs." Order 2, ECF No. 30.

of the '623 patent." Appellee's Br. 28, 28–29; *see id.* at 27–38.

A. Article III Standing Requirements in an Appeal from a Final Agency Action

"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*, 570 U.S. 693, 704 (2013) (explaining that Article III discusses the powers granted to the judiciary 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 [action], and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo*, 136 S. Ct. at 1547 (citations omitted); *see Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 150 (2010) (setting forth these three criteria for standing to challenge the decision of a lower tribunal).[5] The party seeking judicial review, here Altaire, bears the burden of establishing that it has standing on appeal. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006).

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[5] 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 a post-grant review. 35 U.S.C. § 141(c) (2012) ("A party to . . . a post-grant review who is dissatisfied with the final written decision of the [PTAB] . . . may appeal the [PTAB]'s decision only to the . . . Federal Circuit.").

As to the first element, "[t]o establish injury in fact, a[n appellant] must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). A "concrete" injury must "actually exist" but may be either "tangible" or "intangible." *Id.* at 1548, 1549; *see id.* at 1549 (explaining that "the risk of real harm" may "satisfy the requirement of concreteness"). An injury is "particularized" if it affects an appellant "in a personal and individual way." *Id.* at 1548 (internal quotation marks and citation omitted); *accord Hollingsworth*, 570 U.S. at 705.

We recently "established the legal standard for demonstrating standing in an appeal from a final agency action," including "the burden of production[,] the evidence an appellant must produce to meet that burden[,] and when an appellant must produce that evidence." *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1172 (Fed. Cir. 2017) (footnote omitted). We explained that "[a]n appellant's obligation to establish 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 that appellant with a right to appeal." *Id.* at 1172 n.2 (internal quotation marks and citation omitted); *see* 35 U.S.C. § 141(c).

B. Altaire Has Demonstrated Injury in Fact

In support of its Opposition, Altaire appended a declaration of Altaire's general counsel, Michael Sawaya. *See* Altaire's Opp'n to Paragon's Mot. to Dismiss Ex. 1, ECF No. 25 ("Sawaya Opp'n Decl.").[6] Michael Sawaya testified

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[6] Paragon does not contest that Altaire's affidavit satisfies the summary judgment burden of production, *see generally* Appellee's Br., which may be satisfied by an

that "Altaire intends to resume marketing its proprietary formulation of the . . . product[s] in the event the . . . Agreement is terminated early as is sought by Paragon in the concurrent district court litigation in the Eastern District," placing Altaire "under near immediate threat of termination of the Agreement." Sawaya Opp'n Decl. ¶ 16; *see id.* ¶¶ 18–19. Michael Sawaya further testified that Paragon previously sought to terminate the Agreement in the U.S. District Court for the District of Oregon but that the action was dismissed. *Id.* ¶ 17. According to Michael Sawaya, "Altaire believes that Paragon will inevitably sue Altaire for patent infringement upon Altaire filing an [Abbreviated New Drug Application ('ANDA')] with the FDA," such that "invalidating the '623 patent in the post-grant review proceeding that is the subject of this appeal is imperative to removing that patent as an obstacle to the filing and approval of Altaire's ANDA." *Id.* ¶ 22.

Altaire has sufficiently demonstrated imminent harm. Although "a fear of future harm that is only subjective is not an injury or threat of injury . . . that can be the basis of an Article III case or controversy," *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (citation omitted), "the threat of future injury" may be sufficient to establish injury in fact if the "threat was real[and] imminent," *id.* at 1339; *see Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (stating that "proving a reasonable apprehension of suit is . . . one of many ways a [party] can . . . establish that an action presents a justiciable Article III controversy"). Here, Paragon is actively seek-

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affidavit and which requires the party seeking "review of a final agency action [whose] standing [has] come[] into doubt" to produce evidence of standing "at the earliest possible opportunity," *Phigenix*, 845 F.3d at 1172–73.

ing a declaratory judgment that it has the right to terminate the Agreement in the Eastern District. *See* J.A. 1881–82 (asserting a count for "Declaratory Judgment: Right to Terminate" that lists Altaire's alleged prior material breaches and states that "Altaire's prior material breaches under the Agreement entitle Paragon to terminate the Agreement and to seek all appropriate damages"). Even if Paragon does not terminate the Agreement, it will expire in 2021. *See* J.A. 1909. Once the Agreement is terminated, "Altaire intends to file . . . an ANDA," Sawaya Opp'n Decl. ¶ 19, and "to resume marketing its proprietary formulation of the . . . product[s]," *id.* ¶ 16, and it previously has demonstrated its production and marketing capabilities, such that it will be able to resume operations without difficulty, *see id.* ¶ 5. Moreover, Michael Sawaya testified to the imminence of Paragon's infringement suit, *see id.* ¶ 22, and Paragon refused to stipulate that it will not sue Altaire for infringement of the '623 patent, *see* Oral Arg. at 17:07–18:03, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1487.mp3.

While we recognize that "[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all," *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks and citation omitted), we conclude that, under these circumstances, Altaire's injury is inevitable. Therefore, Altaire has satisfied its burden of production by producing sufficient evidence that the threat of infringement litigation is an injury that is "real" and "imminent." *Prasco*, 537 F.3d at 1339.

Having determined that Altaire faces imminent injury, we next must determine whether that injury is concrete and particularized. *See Spokeo*, 136 S. Ct. at 1548 ("Particularization is necessary to establish injury in fact . . . ."); *id.* ("Concreteness . . . is quite different from particularization."). Here, Michael Sawaya explained

that "invalidating the '623 patent in the post-grant review proceeding . . . is imperative to removing that patent as an obstacle to the filing and approval of Altaire's ANDA for its proprietary product[,] which was misappropriated in the '623 patent by Paragon." Sawaya Opp'n Decl. ¶ 22. Because the Agreement specifically prevents Altaire from manufacturing its products, we conclude that Altaire has suffered a "concrete" harm and is affected "in a personal and individual way." *Spokeo*, 136 S. Ct. at 1548.

Altaire's injury is compounded by the likelihood that it would be estopped from arguing that the '623 patent would have been obvious over Lots #11578 and #11581. Pursuant to the estoppel provision in 35 U.S.C. § 325(e)(2), "[t]he petitioner in a post-grant review . . . may not assert . . . in a civil action . . . that [a] claim is invalid on any ground that the petitioner raised or reasonably could have raised during that post-grant review." While we have explained that "a similar estoppel provision 'does not constitute an injury in fact' when . . . the appellant 'is not engaged in any activity that would give rise to a possible infringement suit,'" *Phigenix*, 845 F.3d at 1175–76 (brackets omitted) (quoting *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014)), this case materially differs from both past cases. As explained above, Altaire's injury is imminent, whereas the appellant in *Consumer Watchdog* "only alleged a general grievance concerning" the challenged patent, *see* 753 F.3d at 1263, and the appellant in *Phigenix* only alleged its aspirations of licensing its patent portfolio, *see* 845 F.3d at 1174. Although we do not decide whether this potential estoppel effect is sufficient independently to establish standing, the estoppel effect in this case further supports Altaire's claimed injury in fact. Therefore, considering these factors collectively, we hold that Altaire has demonstrated injury in fact, *see Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1341 (Fed. Cir. 2007) (stating that the appellant

"remains under the threat of an infringement suit" because the statute of limitations had not yet run and that "this threat of litigation is a present injury creating a justiciable controversy"), such that it has standing to challenge the PTAB's Final Written Decision, *see Phigenix*, 845 F.3d at 1172 n.2.

II. The PTAB Violated the Administrative Procedure Act by Refusing to Consider Mr. Al Sawaya's Testimony, the TMQC-247 Data, and the Optical Rotation Test Data

A. Standard of Review

"We review the [PTAB]'s procedures for compliance with the Administrative Procedure Act [('APA')], 5 U.S.C. § 551 *et seq*. [(2012)]." *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1298 (Fed. Cir. 2016); *see* 5 U.S.C. § 706 (providing that "[t]he reviewing court shall . . . (2) hold unlawful and set aside agency action, findings, and conclusions found to be . . . (A) arbitrary, capricious, *an abuse of discretion*, or otherwise not in accordance with law" (emphasis added)). "We review the PTAB's decision of how it manages its permissive rules of trial proceedings for an abuse of discretion." *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 442 (Fed. Cir. 2015) (citation omitted). "An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the [PTAB] could rationally base its decision." *Id.* (internal quotation marks and citation omitted).

B. Mr. Al Sawaya's Declarations

The PTAB assigned "no weight" to Mr. Al Sawaya's opinion on the TMQC-247 and optical rotation test data in the First Al Sawaya Declaration because Altaire had "failed to timely qualify Mr. [Al] Sawaya as an expert witness in this proceeding." J.A. 9. In reaching this

conclusion, the PTAB "decline[d] to consider the [Second Al] Sawaya [D]eclaration," which purported to qualify Mr. Al Sawaya as an expert, "because it [wa]s improper reply evidence." J.A. 9. We hold that the PTAB abused its discretion by failing to consider Mr. Al Sawaya's testimony.

Here, the First Al Sawaya Declaration extensively discussed the results of the TMQC-247 and optical rotation tests. *See* J.A. 732–61. When Paragon challenged Mr. Al Sawaya's qualifications to testify and personal knowledge of the tests, *see* J.A. 1112–15, Altaire submitted the Second Al Sawaya Declaration, *see* J.A. 1418–21, and appended a copy of Mr. Al Sawaya's résumé, *see* J.A. 1423–25. The Second Al Sawaya Declaration demonstrates Mr. Al Sawaya's "over [fifty] years of experience in the pharmaceutical industry" and "extensive experience testing and analyzing results for a variety of testing methodologies relevant to the pharmaceutical field, including . . . [HPLC] reports[] and optical rotation reports." J.A. 1418, 1421. Nevertheless, the PTAB ignored Mr. Al Sawaya's qualifications, determining that "the issue here is not whether Mr. [Al] Sawaya qualifies as an expert witness in the abstract; rather, it is whether [Altaire] has properly qualified Mr. [Al] Sawaya as an expert witness with respect to the testimony he has provided *in this proceeding*." J.A. 7. The PTAB erred for two reasons.

First, § 42.65(b) does not require that the affidavit corroborating the technical test or data be submitted by an expert. *Cf. Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950) (stating that, in the context of the doctrine of equivalents, "[p]roof can be made in any form," including "through testimony of experts *or others versed in the technology*" (emphasis added)). *Compare* 37 C.F.R. § 42.65(a) (discussing "[e]xpert testimony"), *with id.* § 42.65(b) (requiring "*an*

affidavit" without limiting it to an expert (emphasis added)).

Second, Paragon challenged Mr. Al Sawaya's qualifications to testify and personal knowledge of the tests in its Patent Owner Response, *see* J.A. 1112–15, so that it was proper for Altaire to submit the Second Al Sawaya Declaration, which "respond[ed] to arguments raised in the corresponding . . . [P]atent [O]wner [R]esponse," 37 C.F.R. § 42.23(b); *see* 5 U.S.C. § 556(d) (entitling a party "to submit rebuttal evidence"); *see also Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1078, 1082 (Fed. Cir. 2015) (holding that a declaration appended to a reply brief "fairly respond[ed] only to arguments made in . . . [the patent owner]'s response," as required by § 42.23(b), and that the patent owner had "a meaningful opportunity to respond," as required by the APA). To the extent the PTAB was concerned about Paragon's ability to respond to the extensive qualifications set forth in the Second Al Sawaya Declaration, the PTAB could have permitted Paragon to file a surreply, *see Belden*, 805 F.3d at 1081 (stating that the PTAB "has long granted permission to file surreplies despite the absence of any regulation providing for such filings" (footnote omitted)), as Paragon requested, *see* J.A. 1724.

Although the PTAB "has broad discretion to regulate the presentation of evidence," *Belden*, 805 F.3d at 1081, that discretion is not without limits, *see Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1274 (Fed. Cir. 2017) (stating that "[t]he agency does not have unfettered discretion in [evidentiary] matters"). The PTAB's decision to assign no weight to Mr. Al Sawaya's testimony was an abuse of discretion. *See id.* at 1275 (holding that the PTAB "abused its discretion when it refused to admit and consider . . . trial testimony"); *cf. Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1325 (Fed. Cir. 2017) (en banc) (plurality opinion) ("[A]n agency's refusal to consider evidence bearing on the issue before it is, by definition,

arbitrary and capricious within the meaning of 5 U.S.C. § 706, which governs review of agency adjudications. That means that the agency must take account of all the evidence of record, including that which detracts from the conclusion the agency ultimately reaches." (citations omitted)). This decision influenced, at least in part, the PTAB's rejection of the TMQC-247 and optical rotation test data. *See* J.A. 14 (rejecting the testimony in the First Al Sawaya Declaration as insufficient), 17 (rejecting the TMQC-247 test data because Altaire had not "point[ed] to any credible evidence accompanying the Petition"), 19 (rejecting the optical rotation test data because Altaire had not identified "any credible evidence" and "ha[d] not provided any affidavit" in support). On remand, the PTAB must consider Mr. Al Sawaya's testimony when evaluating the reliability of the TMQC-247 and optical rotation test data.

C. TMQC-247 Test Data

Regarding the TMQC-247 test results, the PTAB determined that Altaire had not "point[ed] to any credible evidence accompanying the Petition that meets the requirements of § 42.65(b)" and, thus, "even if [it] accept[ed Altaire]'s assertion that the HPLC data of Altaire's [p]roduct[s] were generated using its allegedly proprietary HPLC method TMQC-247, [it] g[a]ve no weight to those data." J.A. 17. In reaching that decision, the PTAB refused to consider two exhibits appended to Altaire's Reply that "provide[d] information about the standards and samples['] preparation as well as the procedures for running the [TMQC-247] test." J.A. 15; *see* J.A. 15 ("[Altaire] . . . did not submit the [exhibits] until filing its Reply, when [Paragon] no longer ha[d] the opportunity to respond. As a result, we do not consider Exhibits 1027 and 1028." (citations omitted)); *see also* J.A. 1505–22 (Exhibit 1027), 1523–32 (Exhibit 1028). We conclude that the PTAB abused its discretion by refusing to consider Altaire's Reply evidence.

Given Paragon's past reliance on the TMQC-247 test data before the FDA, Altaire submitted the additional information regarding the TMQC-247 test at the first opportunity at which it reasonably could have been expected. When seeking FDA approval of the NDA, Paragon requested "all the work [Altaire] ha[s] on chiral purity," J.A. 1606, and Altaire responded by sending the additional TMQC-247 test data, J.A. 1602–05. Paragon concedes that it relied upon the TMQC-247 test data to obtain FDA approval of the NDA. *See* J.A. 1602–06; *see also* Oral Arg. at 18:41–19:00 (Q: "Did your client use their testing methods before the FDA?" A: "The client did pass through methods that they gave to the FDA. Yes." Q: "So they relied on those methods? Is that true?" A: "It is true that they relied on their data to provide to the FDA."). As a result, we conclude that Altaire had no reason to suspect that Paragon would later challenge the data, upon which it previously relied, as unreliable before the PTAB.

After Paragon unexpectedly challenged Altaire's TMQC-247 test data for failure to comply with § 42.65(b) in its Patent Owner Response, *see* J.A. 1112–15, Altaire submitted its Reply, appending additional information on the TMQC-247 test, *see* J.A. 1418–25, 1505–606. This included Exhibits 1027 and 1028. *See* J.A. 1505–32. Similar to the Second Al Sawaya Declaration, Altaire properly "respond[ed] to [those] arguments raised in [Paragon's Patent Owner R]esponse" by submitting additional evidence demonstrating the reliability of the TMQC-247 testing method. 37 C.F.R. § 42.23(b); *see* 5 U.S.C. § 556(d); *see also Belden*, 805 F.3d at 1078. To the extent Paragon wished to contest this additional evidence, the PTAB could have permitted Paragon to file a surreply. *See Belden*, 805 at 1081.

In light of Paragon's past reliance on the TMQC-247 test data, we conclude that the PTAB abused its discretion by "refus[ing] to consider evidence" regarding the

reliability of the TMQC-247 testing method. *Aqua*, 872 F.3d at 1325 (citation omitted); *see Ultratec*, 872 F.3d at 1275. On remand, the PTAB shall consider all relevant TMQC-247 information in determining whether Altaire satisfied the requirements of § 42.65(b) and, if it did, whether the TMQC-247 test data render obvious the Asserted Claims.

D. Optical Rotation Test Data

Finally, regarding the optical rotation test, the PTAB determined that Paragon "presented sufficient evidence to challenge the accuracy of estimating enantiomer purity based on the specific rotation," such that it "[was] not persuaded that [Altaire]'s optical-rotation data amount to a preponderance of the evidence to show that Altaire's [p]roduct[s] meet[] the chiral-purity limitations of the [Asserted C]laims." J.A. 19, 20. As with the TMQC-247 test data, Paragon relied upon this optical rotation test data before the FDA. *See* J.A. 783–91. Indeed, the '623 patent itself recognizes that the optical rotation test can be used to determine chiral purity. *See* '623 patent col. 4 ll. 33–34.

Nevertheless, the PTAB rejected the data, stating that, "for the optical rotation data, as for the [TMQC-247] data, [Altaire] has not provided any affidavit in compliance with . . . § 42.65(b)." J.A. 19. However, as explained above, *see supra* Section II.B–C, the PTAB abused its discretion by refusing to consider Mr. Al Sawaya's testimony and the additional information on the TMQC-247 test data. To the extent the PTAB's decision to reject as unpersuasive the optical rotation test data rested upon these erroneous determinations, the PTAB must reconsider the reliability of the optical rotation test data pursuant to § 42.65(b) on remand.

CONCLUSION

We have considered Paragon's remaining arguments and find them unpersuasive. We reverse the U.S. Patent and Trademark Office's Patent Trial and Appeal Board's decision regarding the Al Sawaya Declarations. We vacate the U.S. Patent and Trademark Office's Patent Trial and Appeal Board's determination that the TMQC-247 and optical rotation test data did not satisfy the requirements of 37 C.F.R. § 42.65(b) and that the Asserted Claims would not have been obvious over Lots #11578 and #11581. We remand for further consideration consistent with this opinion. Accordingly, the Final Written Decision of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board is

REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

Costs to Altaire.

United States Court of Appeals for the Federal Circuit

ALTAIRE PHARMACEUTICALS, INC.,
Appellant

v.

PARAGON BIOTECK, INC.,
Appellee

2017-1487

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2015-00011.

SCHALL, *Circuit Judge*, dissenting.

My concern in this case is with the issue of standing. In my view, Altaire has failed to establish that it has standing to bring this appeal. I therefore would dismiss for lack of jurisdiction.

I.

Under Article III of the Constitution, in order for a court to have jurisdiction to decide a case, the case must present an actual "case or controversy." *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013). Standing to sue is a necessary component of an Article III case or controversy. *Id.* In order to have standing, a plaintiff or, as in this case, an appellant "must have (1) 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." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Altaire bears the burden of establishing that it has standing. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006).

As the majority opinion makes clear, the standing issue in this case turns on the injury-in-fact requirement. Under that requirement, an appellant must allege an injury "that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Spokeo*, 136 S. Ct. at 1548 (internal quotation marks and citation omitted). For the reasons set forth below, I believe that Altaire has failed to demonstrate that it is threatened with imminent harm, the only type of harm asserted in this case. It thus has failed to show that it has suffered an injury in fact. It therefore lacks standing.

II.

The undisputed facts are these: In 2011, Altaire and Paragon entered into an agreement to pursue U.S. Food and Drug Administration ("FDA") approval for Altaire's phenylephrine hydrochloride products (the "Agreement"). By its terms, the Agreement terminates on May 30, 2021. *See* Joint Appendix ("J.A.") 1909. Subsequently, a dispute arose between the parties, which apparently led Altaire to file two lawsuits in federal court in the Eastern District of New York. In the first suit, *Altaire Pharmaceuticals, Inc. v. Paragon BioTeck, Inc.*, Case No. 2:15-cv-02416 (E.D.N.Y.) ("the breach of contract suit"), Altaire alleges that Paragon breached the Agreement by, among other things, disclosing Altaire's confidential and proprietary product information in its patent application and in its resulting U.S. Patent No. 8,859,623 ("the '623 patent"). *See* Complaint and Jury Demand at 7 (No. 2:15-cv-02416) (E.D.N.Y. April 28, 2015). Paragon has denied Altaire's allegations, has alleged that Altaire has materially

breached the Agreement, and has counterclaimed for, among other things, a declaratory judgment giving it the right to terminate the Agreement prior to its 2021 termination date. Paragon BioTeck, Inc.'s Answer, Affirmative Defenses, Counterclaims, and Third-Party Complaint at 9, 22 (No. 2:15-cv-02416) (E.D.N.Y. Aug. 14, 2015).

In the second suit, *Altaire Pharmaceuticals, Inc. v. Paragon BioTeck, Inc.*, Case No. 1:17-cv-01837 (E.D.N.Y.) ("the inventorship suit"), Altaire alleges, among other things, that the '623 patent is invalid for failure to name the inventor, and it seeks correction of inventorship. Complaint and Jury Demand at 27, 29, 32, and 37 (No. 1:17-cv-01837) (E.D.N.Y. April 3, 2017). The inventorship suit is currently stayed pursuant to 35 U.S.C. § 325(a)(2).

III.

I start from the premise that the standing issue in this case turns entirely on the pending litigation in the Eastern District of New York. I say that because, although both Altaire and the majority point to the Agreement's 2021 termination date, Appellant's Br. 47–48, Majority Op. at 12, I am unable to see how the fact that the Agreement is scheduled to terminate in 2021 supports standing at this point. Put most simply, what we have is a situation in which the parties to a contract that is due to terminate in approximately three years are in a dispute. At the same time, in view of the terms of the Agreement, Altaire cannot infringe the '623 patent while the Agreement is in effect. These circumstances, it seems to me, come nowhere near providing Altaire with grounds for claiming that it is subject to imminent harm. Timing is important for a showing of imminence, or immediacy. The longer the time between when suit is initiated and when potential infringement may occur, "the more likely the case lacks the requisite immediacy." *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). *See Lang v. Pacific Marine and*

Supply Co., Ltd., 895 F. 2d 761, 764–65 (Fed. Cir. 1990) (insufficient evidence of standing to seek a declaratory judgment of patent infringement where "[t]he accused infringing ship's hull would not be finished until at least nine months after the complaint was filed"). Thus, in my view, the fact that the Agreement terminates in 2021 cannot support standing.

IV.

I turn now to the breach of contract suit.* In that regard, the majority rests its conclusion that Altaire has demonstrated imminent harm upon three considerations. The first consideration is the fact that, in the breach of contract suit, Paragon is seeking a declaratory judgment that it has the right to terminate the Agreement prior to its 2021 termination date. Majority Op. at 11–12. The second consideration consists of statements made by Michael Sawaya, Altaire's general counsel, in paragraph 22 of his February 24, 2017 declaration submitted in support of Altaire's opposition to Paragon's motion to dismiss. *Id.* at 10–11. There, Mr. Sawaya states that "Altaire believes that Paragon will inevitably sue Altaire for patent infringement upon Altaire filing an [Abbreviated New Drug Application ("ANDA")] with the FDA." Altaire's Opp'n to Paragon's Mot. to Dismiss at Ex. 1, ECF No. 25 at ¶ 22. Continuing, Mr. Sawaya states that "Altaire therefore believes that invalidating the '623 patent in the post-grant review proceeding that is the subject of this appeal is imperative to removing that patent as an object to the filing and approval of Altaire's ANDA for its proprietary product which was misappropriated in the '623 patent by Paragon." *Id.* And third, the

* Neither Altaire nor the majority points to the inventorship suit as a factor to be considered in the standing analysis.

majority notes that, when questioned at oral argument, counsel for Paragon declined to stipulate that Paragon will not sue Altaire for infringement of the '623 patent. Majority Op. at 12. The majority recognizes that "[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Id.* (quoting *Texas v. United States*, 523 U.S. 296, 300 (1998)) (internal quotation marks and citation omitted). However, it concludes that, under the circumstances of this case, as outlined above, "Altaire's injury is inevitable." *Id.* at 12.

V.

I am unable to agree with the majority that Altaire has demonstrated imminent harm. First, leaving aside the possibility of a settlement, one of two things will happen in the breach of contract suit. Either Altaire will prevail; or Paragon will prevail, in which case Paragon *perhaps* will be given the right to terminate the Agreement. At this point, though, we do not know what will happen. Moreover, should Altaire prevail in the suit, the possibility that Paragon will be given the right to terminate the Agreement before 2021—which is a critical linchpin of Altaire's claim of imminent harm—will have been eliminated. It seems to me that, by any standard, we presently are in a situation where a determination of imminent harm is speculative. *See First Data Corp. v. Inselberg*, 870 F.3d 1367, 1375 (Fed. Cir. 2017). In that case, First Data sought, among other things, a declaratory judgment of noninfringement. Citing *Texas v. United States*, we stated that a claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated or may not occur at all, 870 F.3d at 1375 (citations omitted). We then concluded that because the parties against whom First Data and its co-plaintiff had brought the declaratory judgment action did not currently have an ownership interest in the patents at issue, any potential infringement claim relied on the

"contingent future event" of recovering title to the patents at issue. That, in turn required a court to invalidate an assignment agreement, and only if that case were successful could the patent claims no longer be contingent on a future event that "may not occur at all." *Id.* *See also Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1280–81 (Fed. Cir. 2014) (no standing where Sandoz did not demonstrate that certain future possibilities for changing or eliminating the patent dispute were so unlikely to arise that they should not play a significant role in the Article III determination; the events exposing Sandoz to infringement liability "may not occur as anticipated, or indeed may not occur at all") (quoting *Texas v. United States*, 523 U.S. at 300)).

I also do not believe that Altaire is helped by Mr. Sawaya's declaration. As noted, the primary concern expressed by Mr. Sawaya is the threat of a patent infringement suit by Paragon in the event Altaire files an ANDA with the FDA, should the Agreement be terminated. Mr. Sawaya's belief is based upon the contingency of the Agreement being terminated—either in three years, or upon Paragon's prevailing on its declaratory judgment claim in the breach of contract suit. Either way, for the reasons discussed above relating to the scheduled, or possible, termination of the Agreement, I do not believe Mr. Sawaya's belief can support a claim of imminent harm.

It is true that where Congress has accorded a litigant the right to appeal an administrative decision, the requirement of immediacy, or imminence, for standing may be relaxed. *Consumer Watchdog v. Wis. Alumni Research Found.,* 753 F.3d 1258, 1261 (Fed. Cir. 2014) (citing *Massachusetts v. E.P.A.*, 549 U.S. 497, 517–18 (2007)). However, "[a]lthough imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes." *Defs. of Wildlife*,

504 U.S. at 565, n. 2. I believe that finding imminent harm in the circumstances of this case would stretch immediacy—even a relaxed concept of immediacy—beyond its breaking point.

Finally, I discount, as a factor in the equation, the refusal of counsel for Paragon to stipulate at oral argument that Paragon will not sue Altaire for patent infringement. Quite simply, in view of the contentions of the parties and the posture of the litigation in the Eastern District of New York, I do not see how counsel could have agreed to such a stipulation.

For the foregoing reasons, I conclude that Altaire has failed to demonstrate a threat of imminent harm and, thus, injury in fact.

I note one additional point. The majority posits that Altaire's injury is compounded by the likelihood that, if it does not challenge the Board's decision before us, it could be estopped from arguing that the '623 patent would have been obvious over Altaire's Lots #11578 and #11581. Majority Op. at 13–14. The majority states, "Although we do not decide whether this potential estoppel effect is sufficient independently to establish standing, the estoppel effect in this case further supports Altaire's claimed injury in fact." *Id.* at 13. I do not agree that concerns of estoppel can help carry the day for Altaire. Estoppel "'does not constitute an injury in fact' when . . . the appellant 'is not engaged in any activity that would give rise to a possible infringement suit,'" *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1175–76 (Fed. Cir. 2017) (quoting *Consumer Watchdog*, 753 F.3d at 1262). Here, Altaire currently is under contract through May of 2021 to manufacture, and supply Paragon with, phenylephrine hydrochloride products. *See* J.A. 1909–10. Thus, the Agreement prevents Altaire's activities from constituting infringement until it ends by its own terms in 2021, unless Paragon prevails in the breach of contract dispute,

is given the right to terminate the Agreement, and actually terminates it. In short, currently Altaire is not engaged in any activity that would give rise to a possible infringement suit.

CONCLUSION

Based upon the foregoing, I believe that Altaire has failed to demonstrate that it has suffered an injury in fact. In my view, it thus has failed to carry its burden of establishing that it has standing. Accordingly, I would dismiss its appeal. I therefore respectfully dissent.