United States Court of Appeals for the Federal Circuit

ALLGENESIS BIOTHERAPEUTICS INC.,
Appellant

v.

CLOUDBREAK THERAPEUTICS, LLC,
Appellee

2022-1706

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2020-01438.

Decided: November 7, 2023

DONALD J. MIZERK, Husch Blackwell LLP, Chicago, IL, argued for appellant. Also represented by PHILIP D. SEGREST, JR.

NITIKA GUPTA FIORELLA, Fish & Richardson P.C., Wilmington, DE, argued for appellee. Also represented by SARAH JACK, Minneapolis, MN.

Before MOORE, *Chief Judge*, STOLL and CUNNINGHAM, *Circuit Judges*.

MOORE, *Chief Judge*.

Allgenesis Biotherapeutics Inc. (Allgenesis) appeals from an *inter partes* review final written decision in which the Patent Trial and Appeal Board held that Allgenesis failed to prove claims 4 and 5 of U.S. Patent No. 10,149,820 are unpatentable. Because Allgenesis has failed to establish an injury in fact sufficient to confer standing to appeal, we dismiss.

BACKGROUND

Cloudbreak Therapeutics, LLC (Cloudbreak) owns the '820 patent, which discloses compositions and methods for treating pterygium. '820 patent at 1:19–22. Pterygium is an eye condition in which a tumor-like growth extends from the nasal or temporal side of the eye to the cornea. *Id.* at 1:26–31, 5:61–63. Historically, the only treatment option was surgery to remove the growth. *Id.* at 6:36–42. This surgery, however, provides no guarantee against tumor recurrence. *Id.* Recognizing these drawbacks, the '820 patent sought to provide a new treatment option for pterygium—administering multikinase inhibitors[1] to the eye to inhibit specific growth factors that contribute to tumor growth and hyperemia (i.e., eye redness). *Id.* at 6:49–7:2, 7:19–21, 11:17–20. The patent discloses that nintedanib in particular "may be one of the most powerful multikinase inhibitors for reducing corneal neovascularization," i.e., new blood vessel growth on the front part of

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[1] The term "multikinase inhibitor" refers to "drug compounds (e.g., a small molecule) that reduce or inhibit the expression or activity of two or more kinases, including, for example, intracellular and/or cell surface protein kinases." '820 patent at 8:28–32. Examples of multikinase inhibitors include nintedanib, pazopanib, and sunitinib. *Id.* at 8:47–56.

the eye that is associated with hyperemia and pterygia. *Id.* at 12:3–7; *see also id.* at 18:2–17.

Claim 4, which depends from claims 1 and 3, is representative and recites:

> 1. [disclaimed] A method for reducing hyperemia or symptoms thereof in pterygium in an affected eye of a subject in need of such treatment, without surgically excising a pterygium, comprising administering to the affected eye of the subject a therapeutically effective amount of a multikinase inhibitor.
>
> 3. [disclaimed] The method of claim 1, wherein the multikinase inhibitor is administered to the affected eye in the form of topical ocular formulation or ocular implant.
>
> 4. The method of claim 3, *wherein the multikinase inhibitor is nintedanib* and the nintedanib is administered to the affected eye in the form of a topical ocular formulation and is administered topically to the affected eye.

Id. at 24:33–37, 48–54 (emphasis added).

Allgenesis petitioned for IPR of all eleven claims of the '820 patent. After the Board instituted, Cloudbreak disclaimed the genus claims, i.e., claims 1–3 and 6–11, leaving only claims 4 and 5, which more narrowly claim the use of nintedanib.

The Board issued a final written decision holding Allgenesis failed to show claims 4 and 5 are unpatentable. *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC*, No. IPR2020-01438, 2022 WL 496909 (P.T.A.B. Feb. 15, 2022) (*Decision*). The Board first determined Allgenesis failed to show the claims were anticipated by, or would have been obvious over, Allgenesis' PCT Application Publication No. WO 2016/209555 (Allgenesis' PCT). *Id.* at *8–

27. Specifically, the Board determined Allgenesis' PCT, which claims priority to a U.S. provisional application filed June 22, 2015, does not qualify as prior art because claims 4 and 5 may claim priority to Cloudbreak's U.S. Provisional Application No. 62/172,063 (the '063 provisional), filed June 6, 2015. *Id.* In reaching this priority determination, the Board found the '063 provisional provides sufficient written description support for claims 4 and 5. *Id.* at *12–17.

The Board also determined Allgenesis failed to show claims 4 and 5 would have been obvious over King[2] and Amparo.[3] *Id.* at *27–35. The Board determined a skilled artisan would have been motivated to combine the references with a reasonable expectation of success. *Id.* at *27–33. But it ultimately held the claims were not unpatentable in light of objective indicia of nonobviousness, namely unexpected results. *Id.* at *33–35. The Board credited the '820 patent's description of the unexpected result that nintedanib provides improved efficacy and has a better safety profile compared to the closest prior art, sunitinib. *Id.* (citing '820 patent at Table 2, 11:17–24, 12:1–20, 18:2–18).

Allgenesis appeals, challenging the Board's finding that the '063 provisional provides written description support for claims 4 and 5 and its unexpected results analysis.

DISCUSSION

We have jurisdiction to review final decisions of the Board under 28 U.S.C. § 1295(a)(4)(A). However, Article

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[2] U.S. Patent Application Publication No. 2013/0012531.

[3] Amparo et al., *Safety and Efficacy of the Multitargeted Receptor Kinase Inhibitor Pazopanib in the Treatment of Corneal Neovascularization*, 54 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 537–44 (2013).

III of the U.S. Constitution limits our jurisdiction to the adjudication of "Cases" or "Controversies." U.S. Const. art. III, § 2, cl. 1. To establish a case or controversy, a party invoking federal jurisdiction must meet the "irreducible constitutional minimum of standing." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Although a party does not need Article III standing to file an IPR petition or to obtain a Board decision, *see Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016), the party must establish Article III standing once it seeks review of the Board's decision in this Court. *Consumer Watchdog v. Wis. Alumni Rsch. Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014).

To meet the Article III standing requirements, an appellant must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To establish an injury in fact, an appellant must show it has "suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 339 (quoting *Lujan*, 504 U.S. at 560). As the party seeking judicial review, Allgenesis bears the burden of proving it has standing. *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1171 (Fed. Cir. 2017).

Allgenesis asserts it has standing to appeal the Board's decision based on (1) its potential infringement liability and (2) the Board's priority determination. We conclude Allgenesis has failed to meet its burden to establish standing on either ground.

A

Allgenesis first argues it has suffered an injury in fact based on the potential infringement liability stemming from its development of nintedanib treatments for pterygium. Where an appellant relies on potential infringement liability as a basis for injury in fact, "it must establish that

it has concrete plans for future activity that creates a substantial risk of future infringement or likely cause the patentee to assert a claim of infringement." *JTEKT Corp. v. GKN Auto. LTD.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018). In support of standing, Allgenesis submitted a declaration from its Vice President of Finance, Jack Chang. J.A. 5139–45. Mr. Chang testifies that Allgenesis has been and is continuing to develop formulations of nintedanib for the treatment of pterygium and "reasonably expects that Cloudbreak will seek to enforce [the '820 patent] against any product brought to market." J.A. 5144 ¶ 25; *see* J.A. 5140 ¶ 5. Mr. Chang, however, fails to identify any specific, concrete plans for Allgenesis to develop a nintedanib product that might implicate claims 4 and 5 of the '820 patent.

Mr. Chang testifies that "Allgenesis is engaged in research and clinical trials" to develop its nintedanib product but points only to a Phase II clinical trial completed over three years ago and a related 2020 publication. J.A. 5140–41 ¶ 6. He does not identify any of Allgenesis' development activities since the completion of its Phase II trial in 2020 or its plans for future clinical development. For example, he has not identified any plans to conduct Phase III trials[4] or seek FDA approval.

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[4] Allgenesis asserted in its briefing and at oral argument that it plans to engage in Phase III trials. Appellant's Opening Br. at 2; Oral Arg. at 10:08–26, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-1706_10042023.mp3. However, there is no record support for this assertion, as Mr. Chang's declaration makes no mention of Phase III trials. *See Phigenix*, 845 F.3d at 1173 ("[A]n 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.'" (quoting *Sierra*

Rather, Mr. Chang generically states that "Allgenesis has not abandoned its development of nintedanib and is continuing to devote resources to the development of this project." J.A. 5144 ¶ 25; *see also* J.A. 5141 ¶ 8 ("Allgenesis continues to invest in and pursue this project."); J.A. 5144 ¶ 26 (describing Allgenesis' past expenditures and the "likely" future cost of bringing the product to market); J.A. 5145 ¶ 28 ("Allgenesis's concrete future plans to continue to develop and bring to market its own nintedanib treatments for pterygium pose a substantial risk that Cloudbreak will sue Allgenesis in the future alleging infringement of the '820 patent."). Such conclusory testimony is insufficient to establish that Allgenesis has any *concrete* plans to develop and bring to market a nintedanib treatment for pterygium.

Beyond this, Allgenesis has not shown its activities will create a substantial risk of infringement or will likely cause Cloudbreak to assert a claim of infringement. Allgenesis directs us to settlement conversations between the parties relating to Allgenesis' IPR petition. J.A. 5142–44 ¶¶ 13–17, 19, 21–22, 24 (Chang Decl.). Mr. Chang explains "the parties were unable to reach a mutually agreeable settlement that could remove the likelihood of litigation for patent infringement when Allgenesis brings its product to market." J.A. 5144 ¶ 24. These conversations merely show that *Allgenesis* reached out to Cloudbreak in relation to Allgenesis' IPR petition. J.A. 5142 ¶¶ 14–15; *see also* Oral Arg. at 27:44–28:00. Such evidence is insufficient to show its activities will create a substantial risk of infringement, especially given that Allgenesis has made no assertion that Cloudbreak has sued or threatened to sue Allgenesis if it brings a nintedanib product to market. *See AVX Corp. v. Presidio Components, Inc.*, 923 F.3d

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Club v. E.P.A., 292 F.3d 895, 899 (D.C. Cir. 2002)) (second alteration in original)).

1357, 1365 (Fed. Cir. 2019) ("[Petitioner]'s suspicion that [Patent Owner] would assert the upheld claims against [Petitioner] if it had a reasonable basis for doing so does not mean that there is any reasonable basis right now." (internal citation omitted)).

Allgenesis has failed to establish it has nonspeculative, concrete plans for future activity that creates a substantial risk of future infringement. We therefore conclude Allgenesis has failed to show an injury in fact based on potential infringement liability.

B

Allgenesis also argues it has suffered an injury in fact based on the Board's priority determination. Specifically, the Board determined claims 4 and 5 of the '820 patent are entitled to the June 6, 2015 priority date of the '063 provisional. *Decision*, 2022 WL 496909, at *27. Based on this, the Board determined Allgenesis' PCT, which has a later effective filing date of June 22, 2015, is not prior art. *Id.* at *27. According to Allgenesis, because claims 4 and 5 of the '820 patent and Allgenesis' PCT both relate to the same invention (i.e., nintedanib treatments for pterygium), the Board's relative priority determination affects the scope Allgenesis' own patent rights.

Allgenesis asserts it suffered an injury in fact because the Board's determination will have a preclusive effect on the scope of its pending patent application, Ser. No. 17/750,400, which claims priority to Allgenesis' PCT. *See* Oral Arg. at 7:40–54. Allgenesis has not established that the Board's decision will have preclusive effect. Again, Allgenesis' allegations of harm are not sufficiently specific to establish any injury in fact.

We rejected a similar preclusion argument in *Best Medical International, Inc. v. Elekta Inc.*, 46 F.4th 1346 (Fed. Cir. 2022). There, we held the patentee lacked standing to appeal a Board decision holding a claim unpatentable

because the patentee cancelled the claim before filing a notice of appeal. *Id.* at 1351–52. The patentee argued that certain "collateral estoppel effects" resulting from the Board's decision, including that an examiner in a related reexamination proceeding relied on the Board's analysis, conferred standing. *Id.* at 1352. We rejected this argument, reasoning that collateral estoppel does not apply to non-appealable judgments and the patentee thus would be able to challenge the examiner's findings and conclusions in the reexamination proceeding on appeal. *Id.* at 1352–53. We further explained, "the potential for collateral consequences is insufficient, on its own, to confer standing." *Id.* at 1353 (internal citation and quotation marks omitted).

While *Best Medical* involved different facts, the reasoning is applicable here. Collateral estoppel will not attach to the Board's non-appealable priority determination. *See SkyHawke Techs., LLC v. Deca Int'l Corp.*, 828 F.3d 1373, 1376 (Fed. Cir. 2016). If the examiner were to reach the same priority determination during prosecution of Allgenesis' pending application, Allgenesis can challenge that determination in a separate appeal. Allgenesis has, based on these quite vague allegations, failed to establish a concrete injury.

Beyond any preclusive effect, Allgenesis argues the Board's determination will still have a practical impact on the scope of its patent rights. Oral Arg. at 8:26–33, 8:58–9:15. The problem with this argument is that Allgenesis has failed to articulate with any specificity how the Board's priority determination will impact its issued patents or pending continuation applications which claim priority to its PCT application. Allgenesis' argument on this point is limited to a single paragraph containing only vague allegations in its opening brief and reply brief, respectively. *See* Appellant's Opening Br. at 3–4 ("[T]he Board's determination as to the scope of the disclosure of the '063 provisional and the relative priority of the '820 patent in comparison

to Allgenesis's own patents and pending applications also affects or may affect . . . Allgenesis's patent rights and the issued or still-pending continuation applications claiming priority to that application."); Appellant's Reply Br. at 12–13 ("The Board's specific priority finding, in the Final Written Decision that is the subject of this appeal, injures Allgenesis by impairing Allgenesis's own patent rights."). Allgenesis' general and nonspecific allegations are insufficient to meet its burden of establishing standing. Under these circumstances, Allgenesis has failed to show it has suffered any concrete injury in fact based on the Board's priority determination.

CONCLUSION

For these reasons, we conclude Allgenesis has failed to establish an injury in fact sufficient to confer Article III standing. We dismiss the appeal and do not reach the merits of the Board's decision.

DISMISSED

COSTS

No costs.