No. 20-779

IN THE

Supreme Court of the United States

ARGENTUM PHARMACEUTICALS LLC,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

JANE M. LOVE, PH.D.
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000

MARK A. PERRY
Counsel of Record
JACOB T. SPENCER
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
MPerry@gibsondunn.com

Counsel for Respondent

QUESTION PRESENTED

Any party seeking judicial review of a final written decision by the Patent Trial and Appeal Board must establish Article III standing. Accordingly, petitioner submitted declarations regarding the injury it allegedly would suffer from the Board decision at issue in this case. The Federal Circuit reviewed those declarations and made the factual finding that petitioner had failed to adduce "sufficient evidence" to establish injury in fact. The question presented is:

Whether the court of appeals correctly found that petitioner's evidence of alleged injury was insufficient to establish Article III standing.

RULE 29.6 STATEMENT

Respondent Novartis Pharmaceuticals Corporation's parent company is Novartis AG, which is publicly held.

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REGULATION

RULE

BRIEF IN OPPOSITION

Respondent Novartis Pharmaceuticals Corporation ("Novartis") respectfully submits that the petition for a writ of certiorari should be denied.

STATEMENT

In an administrative proceeding, the Patent Trial and Appeal Board ("Board") issued a final written decision concluding that Novartis's patent claims are not unpatentable. Several parties to that administrative proceeding, including petitioner Argentum Pharmaceuticals LLC ("Argentum"), sought review of the Board's decision in the Federal Circuit. After the other challengers settled with Novartis, the court of appeals found that Argentum's evidence was insufficient to establish that it would suffer an injury in fact from the Board's decision—an essential predicate to Article III standing. Accordingly, the Federal Circuit dismissed Argentum's appeal for want of jurisdiction.

A. Legal Framework

1. The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), established a procedure known as "*inter partes* review" through which the United States Patent and Trademark Office is authorized to review the patentability of previously issued patent claims. *See Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018).

Because Article III does not apply to administrative proceedings, any person "who is not the owner of a patent" may petition for *inter partes* review of particular patent claims, regardless of whether it would satisfy constitutional requirements for standing.

35 U.S.C. § 311(a); *see Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2143-44 (2016) ("Parties that initiate the proceeding need not have a concrete stake in the outcome; indeed, they may lack constitutional standing."). If another person has petitioned for *inter partes* review of the same claims, a later petitioner can "join" in the earlier petition. 35 U.S.C. § 315(c).

Upon receiving a petition for *inter partes* review, the Board makes two decisions. The Board, acting on authority delegated by the Director, first decides whether to institute review, which is a discretionary and non-appealable decision. *See* 35 U.S.C. § 314; *Thryv, Inc.* v. *Click-To-Call Techs., LP*, 140 S. Ct. 1367, 1371 (2020). If the Board institutes review, a panel of administrative patent judges presides over a proceeding culminating in a "final written decision" regarding the patentability of the challenged claims. 35 U.S.C. § 318(a).

"A party to an inter partes review . . . who is dissatisfied with" a final written decision of the Board may seek review in the Federal Circuit. 35 U.S.C. § 141(c); *see also id.* § 319.

2. To invoke the Federal Circuit's jurisdiction, however, "an appellant must meet 'the irreducible constitutional minimum of standing.'" *Amerigen Pharm. Ltd.* v. *UCB Pharma GmBH*, 913 F.3d 1076, 1082 (Fed. Cir. 2019) (quoting *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 560 (1992)); *see also Arizonans for Official English* v. *Arizona*, 520 U.S. 43, 64 (1997) ("The standing Article III requires must be met by persons seeking appellate review, just as it must be met by persons appearing in courts of first instance.") These minimum requirements are an (1) injury in fact that is both "concrete and particularized" and "actual

or imminent," and that is (2) traceable to the defendant and (3) likely to be redressed by a favorable decision. *Lujan*, 504 U.S. at 560-61.

The proponent of federal jurisdiction always "bears the burden of establishing these elements." *Lujan*, 504 U.S. at 561. It must establish standing "as of the commencement of" the litigation—in the *inter partes* review context, at the time it files its appeal. *Id.* at 570 n.5. And it must maintain standing "throughout all stages of litigation." *Hollingsworth* v. *Perry*, 570 U.S. 693, 705 (2013).

When standing is challenged or is not self-evident, a person seeking review of a Board decision in the Federal Circuit must discharge its burden by identifying record evidence or submitting additional evidence "at the first appropriate time." *Phigenix, Inc.* v. *Immunogen, Inc.*, 845 F.3d 1168, 1172-73 (Fed. Cir. 2017) (internal quotation marks omitted). This includes evidence that the party has suffered (or imminently will suffer) an injury in fact traceable to the challenged patent claims and redressable by judicial review.

3. Before a manufacturer can market a prescription drug, it must obtain approval from the Food and Drug Administration. Under the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), a would-be producer of a generic version of a previously approved drug can file an abbreviated new drug application ("ANDA") instead of a full new drug application. A "typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to," an already-approved reference drug. *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see* 21 U.S.C. § 355(j). Among other requirements, an ANDA filer must, as to each patent

associated with the reference drug (as listed in the FDA's Orange Book), certify whether the patent is valid and would be infringed by its proposed generic. *See Caraco Pharm. Labs.*, 566 U.S. at 406-08.

In some circumstances, submitting an ANDA is deemed by statute to be an act of patent infringement, "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale" of the generic drug "before the expiration" of patents associated with the reference drug. 35 U.S.C. § 271(e)(2). That act of patent infringement gives the patent holder an immediate right to sue. *See id.* If the patent holder does so within a specified time, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Caraco Pharm. Labs.*, 566 U.S. at 407.

4. "[T]ypically in order to demonstrate the requisite injury in an [*inter partes* review] appeal, the appellant/petitioner must show that it is engaged or will likely engage in an[ ] activity that would give rise to a possible infringement suit or has contractual rights that are affected by a determination of patent validity." *JTEKT Corp.* v. *GKN Auto. LTD.*, 898 F.3d 1217, 1220 (Fed. Cir. 2018) (alteration in original; internal quotation marks and citations omitted).

Because the filing of an ANDA can give rise to an immediate infringement suit, the Federal Circuit has held that an ANDA filer generally has standing to challenge Board decisions related to patents implicated by its ANDA. *See Amerigen Pharm.*, 913 F.3d at 1083.

The Federal Circuit has not, however, ruled that an ANDA is a necessary prerequisite to Article III standing. On the contrary, the court of appeals has

also recognized that a party can demonstrate injury in fact from the risk of an infringement suit even before it files an ANDA. *See Altaire Pharm., Inc.* v. *Paragon Bioteck, Inc.*, 889 F.3d 1274, 1283 (Fed. Cir. 2018). Similarly, the fact that the would-be competitor "has no product on the market" at the time of appeal "does not preclude Article III standing." *JTEKT*, 898 F.3d at 1220.

Whether or not an ANDA has been filed, if standing is challenged or not readily apparent, the party invoking federal jurisdiction must present *evidence*, not mere conclusory assertions, that it is likely to be sued for infringement or faces some other concrete risk of imminent harm. *Compare*, *e.g.*, *E.I. DuPont de Nemours & Co.* v. *Synvina C.V.*, 904 F.3d 996, 1005 (Fed. Cir. 2018) (declarations sufficient to establish standing), *with JTEKT*, 898 F.3d at 1221 (declarations insufficient to show that appellant's "planned product would . . . likely lead to charges of infringement").

B. Factual Background

Novartis holds U.S. Patent No. 9,187,405. Pet. App. 2a. That patent claims methods for using the drug fingolimod to treat relapsing-remitting multiple sclerosis. *Id.* at 18a. Those methods are embodied in use of Gilenya®, the world's first solid oral medicine for treating relapsing-remitting multiple sclerosis. *See id.* at 17a.

According to the declarations it submitted to the court of appeals in September 2018, Argentum is a "young company" that "partners with other companies to develop generic drug products and to bring them to market." Supp. Pet. App. 11a, 13a. Argentum assertedly reached a "collaboration agreement" with KVK-

Tech, a generic pharmaceutical manufacturer, in January 2016. *Id.* at 14a. That agreement—which Argentum did not submit to the Federal Circuit—purportedly provides that the two companies will "collaborate" to develop "pharmaceutical products, including generic drug products"; "prepare, prosecute and defend [*inter partes* reviews] and litigation under the Hatch-Waxman Act"; "share in external costs"; and "share in any financial benefits." *Id.* Argentum declared that "[e]xternal costs are shared by Argentum and KVK on an opportunity-by-opportunity basis" and "[r]esulting revenues from the collaboration are distributed between the parties." *Id.*

Neither Argentum nor KVK has ever sold a generic version of Gilenya®, nor has either filed an ANDA with the FDA seeking regulatory approval to produce or market fingolimod. Rather, according to Argentum's declarations, the two "agreed" in 2017 to develop a generic version of Gilenya®. Supp. Pet. App. 15a. The declarations stated that an ANDA for this generic version would "be filed by KVK," which had "represented" to Argentum's CEO "that the ANDA [would] likely be filed within the next 8-10 months"—i.e., sometime between May and July 2019. *Id.* Argentum declared that both it and KVK had "been diligent in working toward FDA submission of the ANDA" and that it had "invested significant manpower and resources to the endeavor." *Id.* Argentum's declarations did not, however, specify what work (if any) had been done toward the filing of an ANDA, nor did they quantify or provide any details regarding Argentum's purportedly "significant" investment. Argentum speculated that "revenues" from its generic version of Gilenya® would be "$10-50 million per year, with a positive profit margin," although

it did not explain how it arrived at that projection or what its profits might be. *Id.* at 16a.

Argentum's declarations also asserted that "Novartis w[ould] inevitably sue Argentum's manufacturing and marketing partner KVK for patent infringement upon KVK's filing an ANDA." Supp. Pet. App. 17a. The declarations made no prediction regarding any infringement litigation in the absence of an ANDA, or whether and how Argentum would be a proper party to such a lawsuit. And the declarations were silent as to any separate infringement suit against Argentum itself.

C. Proceedings Below

1. In February 2017, Apotex Inc. and Apotex Corp. (together, "Apotex") filed a petition for *inter partes* review of Novartis's patent claims. Pet. App. 85a. The Board instituted review in July 2017 and granted requests for joinder under 35 U.S.C. § 315(c) from Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., Sun Pharma Global FZE, Teva Pharmaceuticals USA, Inc., Actavis Elizabeth LLC, and Argentum. *Id.* at 2a; *see also id.* at 85a-112a. Except for Argentum, all petitioners in the *inter partes* review proceeding are generic drug makers with filed ANDAs for Gilenya®.[1]

In July 2018, the Board concluded that the *inter partes* review petitioners had not shown that Novartis's patent claims were unpatentable. Pet. App. 13a. All of those petitioners initially appealed the Board's final written decision to the Federal Circuit. But each

[1] Although listed as a real party in interest by Argentum, KVK never sought to join and thus was never a party to the *inter partes* review.

petitioner other than Argentum eventually settled with Novartis, and each of their appeals was dismissed. *See* Appeal No. 18-2260, ECF 74 (Mar. 2019) (dismissing appeals of Teva Pharmaceuticals USA, Inc. and Activis Elizabeth LLC); Appeal No. 18-2230, ECF 125 (Dec. 2019) (dismissing appeals of Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE); Appeal No. 18-2209, ECF 134 (Feb. 2020) (dismissing appeals of Apotex).

2. In August 2018, before merits briefing commenced and before the Federal Circuit had dismissed the other appellants, Novartis moved to dismiss Argentum's appeal for lack of standing. Pet. App. 2a. Argentum opposed that motion and submitted two declarations that purported to establish its standing to seek judicial review, one from the President and CEO of KVK, Anthony Tabasso, the other from its own CEO, Jeffrey Gardner. *See* Supp. Pet. App.1a-4a, 10a-18a; *supra* 5-7. Argentum also submitted several exhibits, none of which mentioned any efforts by Argentum or KVK related to generic Gilenya®. *See* Supp. Pet. App. 5a-9a, 19a-67a. The court of appeals directed the parties to address Argentum's standing in their merits briefs. Pet. App. 2a.

In its opening brief, Argentum argued that the court of appeals need not decide whether it had standing, because the other appellants satisfied Article III's requirements. Pet. App. 2a-3a. Argentum also relied on its previously submitted declarations, without offering any additional evidence or updating the court on its purported efforts to develop a generic version of Gilenya®. *See* Appeal No. 18-2209, ECF 69, at 47-50.[2]

[2] Along with its reply brief (and after Novartis had settled with two of the other seven appellants), Argentum filed a motion to

By the time the Federal Circuit held oral argument in January 2020, all appellants other than Argentum and Apotex had been dismissed. At argument, Argentum again insisted that the court of appeals did not need to address its standing, "because the standing issue is only directed to Argentum" and "Apotex's standing ha[d] not been challenged." Jan. 9, 2020 Tr. at 11:13-21.

A month later, however, Novartis settled with Apotex, leaving Argentum as the sole remaining appellant. Novartis submitted a letter to the court of appeals under Federal Rule of Appellate Procedure 28(j), informing the court that "Article III standing has become a threshold issue." Appeal No. 18-2209, ECF 131, at 2. Novartis also filed a suggestion of mootness, explaining that "[b]ecause Argentum lacks standing, and is now the sole appellant, this appeal is now moot." Appeal No. 18-2209, ECF 132, at 4. In response, Argentum once again relied on its previously submitted declarations to establish standing. *See* Appeal No. 18-2209, ECF 135.

3. On April 23, 2020, the Federal Circuit issued a unanimous opinion dismissing Argentum's appeal. Pet. App. 8a. The panel held that Argentum lacked Article III standing because its declarations were factually insufficient to demonstrate injury in fact. *Id.* at 3a-8a.

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supplement the record with updated declarations. *See* Appeal No. 18-2209, ECF 88-1. The panel denied that motion in December 2019. *See* Appeal No. 18-2209, ECF 121. Argentum does not challenge that ruling in this Court, and thus the two declarations and exhibits submitted at the motion-to-dismiss stage comprise all the record evidence related to Argentum's standing.

The panel first rejected Argentum's assertion that it faced "a real and imminent threat of litigation," Pet. App. 4a, because "[n]o ANDA has been filed here, and Argentum has not provided evidence showing that it would bear the risk of any infringement suit or anything related to its involvement in the ANDA process beyond generic statements," *id.* at 6a.

The panel next rejected Argentum's assertion that it would "incur significant economic injury," because "Argentum has not provided sufficient evidence to establish an injury in fact through economic harm." Pet. App. 6a. Rather, Argentum provided only "generalities," and "conclusory and speculative" assertions "without providing evidence specific to a generic Gilenya® product." *Id.* at 6a-7a.

Finally, the panel rejected Argentum's assertion that it "would be estopped under 35 U.S.C. § 315(e) from raising the patentability and validity issues in a future infringement action" because it had not "established there is a risk of an infringement suit." Pet. App. 7a-8a.

Argentum sought rehearing en banc, which the Federal Circuit denied without calling for a response and without noted dissent. Pet. App. 9a-10a.

REASONS FOR DENYING THE PETITION

The Federal Circuit found that Argentum had offered insufficient evidence to show injury in fact and on that basis held that Argentum lacked Article III standing to appeal. Argentum asks this Court to review the court of appeals' holding that it lacked constitutional standing. But this case does not present either of the questions framed by the petition. The Federal Circuit did not "categorically" preclude joint venture partners who are not manufacturers or

ANDA filers from establishing standing. Pet. i. Nor did the court of appeals "reject[ ]" statutory estoppel as a potential cause of injury in fact. Pet. ii. The Federal Circuit has neither adopted nor applied any such bright-line rules, in this case or any other.

On the contrary, the court of appeals has recognized that a non-manufacturer or ANDA filer *may* have standing, but it must prove its own injury in fact as required by Article III. It could do so by "establish[ing] that it has concrete plans for future activity that creates a substantial risk of future infringement or likely [will] cause the patentee to assert a claim of infringement," *JTEKT Corp.* v. *GKN Auto. LTD.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018), or even that it had made a sufficiently specific "invest[ment]" in the "generic [pharmaceutical] product or ANDA," Pet. App. 7a.

Here, the Federal Circuit applied well-settled law and found that Argentum's declarations were insufficient as a *factual* matter to meet the injury-in-fact requirement. Pet. App. 6a-8a. The only issue properly presented by the judgment below is the Federal Circuit's case-specific finding that Argentum's evidence was insufficient to satisfy Article III's requirements. There is no reason for this Court to review the court of appeals' fact-bound conclusion that Argentum, having been given an opportunity to carry its evidentiary burden, simply failed to do so. Indeed, even a cursory review of the evidence—which Argentum did not include with its petition, but which Novartis attaches to this response for the Court's convenience—demonstrates that the court of appeals' factual finding was entirely correct. And the routine application of long-established standing principles to this factual record does not come close to warranting this Court's review.

I. THE COURT OF APPEALS CORRECTLY CONCLUDED THAT ARGENTUM'S DECLARATIONS WERE FACTUALLY INSUFFICIENT TO DEMONSTRATE STANDING.

As Argentum concedes, the constitutional requirements for standing are well-settled. *See* Pet. 22-23. To invoke the jurisdiction of the Federal Circuit, Argentum was required to show that it had "(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*, 136 S. Ct. 1540, 1547 (2016). It is equally well-settled that while a party need not satisfy Article III to participate in administrative proceedings, *see Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2143-44 (2016), a "person[ ] seeking appellate review" of such proceedings must establish its constitutional standing, *Hollingsworth* v. *Perry*, 570 U.S. 693, 705 (2013). The proponent of federal jurisdiction "bears the burden of establishing standing as of the time" it commenced the proceeding "and maintaining it thereafter." *Carney* v. *Adams*, 141 S. Ct. 493, 499 (2020).

"[T]he requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute." *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 497 (2009). To meet this requirement, a party must show "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan* v. *Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (citation and internal quotation marks omitted). And because standing is not a "mere pleading requirement[ ]," injury in fact "must be supported in the same way as any other matter on which the [party] bears the burden of proof,

i.e., with the manner and degree of *evidence* required at the successive stages of the litigation." *Id.* at 561 (emphasis added).

Here, the Federal Circuit correctly made the factual finding that Argentum's two declarations—the entirety of the evidentiary record on this point—were insufficient to show injury in fact. The court of appeals did not make any bright-line pronouncement that joint venture partners (or pre-ANDA filers) cannot suffer injury, that economic harm is insufficient, or that the statutory estoppel provision may not cause injury in some circumstances. Rather, the court found that the *evidence* as to each of these theories was insufficient to show that Argentum would suffer a concrete and imminent injury. Nothing about that factual finding warrants further review.

A. Argentum Failed To Show That It Faced Any Concrete And Imminent Risk Of Patent Litigation.

1. The Federal Circuit correctly found that Argentum's evidence was insufficient to show that it "face[d] a real and imminent threat of litigation." Pet. App. 4a. The court of appeals has held that a party can satisfy its burden of establishing injury in fact, among other ways, by showing that it "intend[s] to file an ANDA and [is] at imminent risk of being sued." *Id.* at 5a (citing *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274, 1282-83 (Fed. Cir. 2018)). Here, however, Argentum's declarations stated that any ANDA would "be filed by KVK, Argentum's manufacturing and marketing partner." *Id.* at 5a. And Argentum declared that "Novartis will inevitably sue Argentum's manufacturing and marketing partner KVK," not Argentum, if KVK did so. *Id.* at 5a-6a (internal

quotation marks omitted). In short, the record evidence did not even assert that *Argentum* faced any risk of litigation whatsoever.

Moreover, Argentum's declarations failed to show that KVK had any concrete plans to file an ANDA or had taken any substantive step to prepare any portion of an ANDA. Rather, those declarations filed in 2018 stated only that an ANDA was "*likely* [to] be filed within the next 8-10 months." Supp. Pet. App. 15a (emphasis added). Nor did Argentum provide any evidence that any scientific work had been done on preparing an ANDA or to develop a generic version of Gilenya®. *Cf. Altaire Pharm.*, 889 F.3d at 1282-83 (threat of infringement suit was "imminent" when Altaire had previously manufactured and marketed the product and had concrete plans to file an ANDA); *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1083-84 (Fed. Cir. 2019) (finding injury in fact when FDA had already tentatively approved Amerigen's ANDA and only the challenged patent prevented launch of product).

Thus, the Federal Circuit properly rejected as insufficient Argentum's bare assertions that KVK intended to file an ANDA sometime in the future. As this Court recently explained, "an injury in fact requires an intent that is concrete," and the mere expectation of future action is not enough. *Carney*, 141 S. Ct. at 502. And this Court has long held in an analogous context that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007). Argentum

failed to satisfy that standard in these circumstances, because the facts it asserted did not come close to establishing that KVK had any concrete intent to file an ANDA or had taken any specific steps to do so when Argentum appealed to the Federal Circuit. Confirming that conclusion, "[n]o ANDA ha[d] been filed" when the Federal Circuit issued its decision—more than a year and a half after Argentum submitted its declarations. Pet. App. 6a.

2. Contrary to Argentum's assertions, the Federal Circuit did not "categorically . . . preclude redress for injured members of joint ventures in the pharmaceutical industry by only recognizing" manufacturing and marketing partners "as having demonstrable injury-in-fact for Article III standing." Pet. i. Nor did the Federal Circuit "ignore[ ] the threat of indirect infringement allegations." *Id.* at 32.

Although Argentum told the court of appeals that Novartis would sue KVK, not Argentum, *see* Supp. Pet. App. 17a, it now asserts that its joint venture efforts "also give rise to an imminent suit by Novartis against Argentum for *indirect* infringement" for inducing KVK's patent infringement. Pet. 32; *see* 35 U.S.C. § 271(b) ("Whoever actively induces infringement of a patent shall be liable as an infringer.").

Even if Argentum had shown that *KVK* had concrete plans to file an ANDA, its belated assertion that *it* would be sued for inducing that infringement is not supported by any evidence. The Federal Circuit has recognized that, in some circumstances, a joint venturer's efforts relating to an ANDA can induce patent infringement. *See Forest Labs., Inc.* v. *Ivax Pharm., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007) (finding "induced" infringement by Cipla where "the plan to man-

ufacture, import, market, and sell the [patented] products described in the ANDA was undoubtedly a cooperative venture, and Cipla was to manufacture and sell infringing [patented] products to [its venture partner] for resale in the United States"); *cf. AIDS Healthcare Found., Inc.* v. *Gilead Scis., Inc.*, 890 F.3d 986, 993 (Fed. Cir. 2018) ("Jurisdiction for a declaratory action premised on an inducement theory does not arise in the absence of concrete steps [that] have been taken with the intent to conduct activity which could constitute infringement." (internal quotation marks omitted; alteration in original)). But here, the court of appeals concluded that Argentum had not carried its burden because it had "not provided evidence showing that it would bear the risk of any infringement suit or *anything related to its involvement in the ANDA process beyond generic statements*." Pet. App. 6a (emphasis added). This is an evidentiary failure, not a legal rule.

3. Equally unavailing is Argentum's contention that it should be permitted to advance KVK's future interests—for example, if KVK does file an ANDA—on a third-party standing theory. *See* Pet. 27-29. As an initial matter, that argument is not properly before the Court because it was "not pressed or passed upon below"; Argentum never argued, and the court of appeals did not address, third-party standing. *Illinois* v. *Gates*, 462 U.S. 213, 222 (1983).

In any event, Argentum's third-party standing argument is factually and legally meritless. As a matter of fact, KVK would have lacked standing for the same reasons Argentum lacked standing: Its supposed intent to file an ANDA sometime in the future was entirely speculative and unsupported by evidence. And as a matter of law, third-party standing is appropriate

only where there is some "hindrance" preventing the person who possesses the right from protecting its interests. *Kowalski* v. *Tesmer*, 543 U.S. 125, 126 (2004). Argentum's purported agreement that it is "the sole party responsible for representing the Joint Venture's interests in patent-related litigation," Pet. 28, reflects at most KVK's "disinterest" in advancing its own rights, not its "disability," and thus does not qualify as a hinderance to KVK's participation in *inter partes* review or Argentum's appeal. *Sessions* v. *Morales-Santana*, 137 S. Ct. 1678, 1689 (2017); *see also Kowalski*, 543 U.S. at 132 (lack of an attorney is no hindrance to indigent prisoners advancing their own rights).

B. Argentum Failed To Show That It Would Suffer Non-Speculative Economic Injury.

The Federal Circuit likewise found that Argentum had "not provided sufficient evidence to establish an injury in fact through economic harm." Pet. App. 6a. Although Argentum and KVK had purportedly invested in manufacturing facilities, they provided no evidence that those facilities would be used to manufacture "a generic Gilenya® product." *Id.* at 6a-7a. Nor had Argentum "provide[d] sufficient evidence that it invested in KVK's generic Gilenya® product or ANDA," relying instead on "generalities" that it had been "diligent in working toward FDA submission of the ANDA" and "invested significant man-power and resources to the endeavor." *Id.* at 7a. And Argentum's "assertion that it w[ould] suffer at least $10-50 million per year in lost profits once the FDA grants provisional approval to the ANDA [wa]s both conclusory and speculative." *Id.*

Argentum acknowledges the fact-bound nature of the Federal Circuit's finding with respect to its purported economic injury. *See* Pet. 29-30. It argues that the court of appeals should have held that its "sworn declarations" were enough. *Id.* at 31. But those declarations did not show that Argentum had invested any money or resources in actually developing generic Gilenya®, and their assertion of lost profits was purely speculative, especially considering that they did not show any concrete steps even toward preparing or filing an ANDA. Contrary to Argentum's hyperbolic assertion, the Federal Circuit did not invoke Article III "to eliminate an entire class of appellants with a direct financial interest" in *inter partes* review proceedings. *Id.* at 6. Rather, the court of appeals made a routine factual finding that Argentum had failed to prove any such direct financial interest.

For the same reasons, Argentum's argument that it has suffered an economic injury merely because Novartis has an enforceable patent is unavailing. *See* Pet. 25-27. Argentum did not raise this argument in the court of appeals. Unsurprisingly so, given that the Federal Circuit has repeatedly rejected efforts to establish a special exception to Article III's requirements that would permit any *inter partes* review petitioner standing to appeal—and this Court has repeatedly denied review of those holdings. *See*, *e.g.*, *Gen. Elec. Co.* v. *United Techs. Corp.*, 928 F.3d 1349 (Fed. Cir. 2019), *cert. denied sub nom. Gen. Elec. Co.* v. *Raytheon Techs. Corp.*, 140 S. Ct. 2820 (2020); *RPX Corp.* v. *ChanBond LLC*, 780 F. App'x 866 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 2713 (2019); *JTEKT Corp.*, 898 F.3d 1217, *cert. denied*, 139 S. Ct. 2713 (2019). Rather, the court of appeals has required evidence that the would-be appellant "is engaged or will likely engage in an[ ] activity that would give rise to a possible

infringement suit or has contractual rights that are affected by a determination of patent validity." *JTEKT Corp.*, 898 F.3d at 1220 (alteration in original; internal quotation marks and citations omitted).

Here, as the Federal Circuit correctly found, Argentum failed to provide evidence sufficient to make that showing. And it certainly failed to show that it has "a generic product that [would be] ready to launch" but for Novartis's patent claims. Pet. 27. As a result, Argentum's assertion that it would suffer economic injury was "entirely speculative." Pet. App. 6a.

C. Argentum Failed To Show That It Would Actually Be Estopped From Litigating Patent Validity.

Finally, the Federal Circuit correctly found that the possibility of statutory estoppel under 35 U.S.C. § 315(e) did not constitute injury in fact under the circumstances here presented. Pet. App. 7a-8a.

The Federal Circuit's estoppel ruling—like the other two bases for its decision—rested on the factual finding that Argentum had "not established that there is risk of an infringement suit." Pet. App. 7a. Argentum has no answer to the court of appeals' factual finding beyond asserting without support that "it is all but a certainty that the parties will have future litigation." Pet. 33. The *evidence*—the declarations submitted by Argentum itself—does not support that assertion, as the court of appeals recognized. *See* Pet. App. 6a ("Argentum has not provided evidence showing that it would bear the risk of any infringement suit."). Indeed, Argentum's declarations did not even

assert that it would be sued by Novartis. *See* Supp. Pet. App. 17a.[3]

Having failed to establish any reasonable likelihood of an infringement suit, Argentum now complains that "the Federal Circuit's rationale ignores that [estoppel] also automatically applies to *any further proceedings before the Board*," and thus that statutory estoppel has "already attached regardless of whether Argentum is sued for infringement in district court." Pet. 33. But Argentum never argued below that it had standing because it was already estopped from bringing further proceedings before the Board. Rather, it said below that "absent relief from this Court, Argentum would be estopped under 35 U.S.C. § 315(e) from raising the patentability and validity issues *in a highly likely infringement action* over the anticipated ANDA." Appeal No. 18-2209, ECF 69, at 50 (emphasis added). And since Argentum failed to show that it had any concrete or particularized stake in the validity of Novartis's patent claims, its belated estoppel argument makes no difference.

In all events, Argentum could have avoided any statutory estoppel by not joining the *inter partes* review. To the extent that Argentum or KVK is estopped from litigating the validity of Novartis's patent claims, that is the result of Argentum's choice to file a tag-along *inter partes* review application, to name

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[3] Argentum's reliance on *AT&T Corp.* v. *FCC*, 317 F.3d 227 (D.C. Cir. 2003), is accordingly misplaced. That decision involved litigation estoppel, not statutory estoppel. *See id.* at 237. And the D.C. Circuit concluded that the collateral estoppel effect of the agency decision there supported standing because it would harm the petitioner "in *pending* litigation." *Id.* (emphasis added). Here, the Federal Circuit found that there was no pending—or imminent—litigation.

KVK as a real party in interest without attempting to join KVK, and to "acquiesce[ ] in the dismissal" of its appeal without moving to vacate the Board's decision. *See United States* v. *Munsingwear, Inc.*, 340 U.S. 36, 40 (1950). This Court has denied three recent certiorari petitions challenging the Federal Circuit's standing decisions and invoking estoppel under 35 U.S.C. § 315(e). *See Gen. Elec. Co.*, 140 S. Ct. 2820; *RPX Corp.*, 139 S. Ct. 2713; *JTEKT Corp.*, 139 S. Ct. 2713. Argentum's cursory estoppel argument fails even to mention those denials, much less to explain why the result should be different here.

* * *

Tellingly, Argentum does not attempt to argue that the question presented is important to anyone other than itself. Any petitioner dissatisfied with a final written decision of the Board can obtain Federal Circuit review, so long as it satisfies Article III's requirements. For example, a would-be generic manufacturer (or marketing partner) could show injury in fact by "establish[ing] that it has concrete plans for future activity that creates a substantial risk of future infringement or likely [will] cause the patentee to assert a claim of infringement." *JTEKT Corp.*, 898 F.3d at 1221; *see also AVX Corp.* v. *Presidio Components, Inc.*, 923 F.3d 1357, 1365 (Fed. Cir. 2019) (noting that a would-be challenger would have standing "if the [patent] claim would block the challenger's own current or nonspeculative actions in the rivalry for sales"). Argentum simply failed to carry its burden of proof, as the court of appeals correctly found.

II. THE QUESTION PRESENTED IS FACT-DEPENDENT, AND THIS CASE IS A POOR VEHICLE FOR CONSIDERING IT.

The only issue properly raised by Argentum's petition is whether the court of appeals misapplied well-settled law—including Federal Circuit precedent—in concluding that Argentum's evidence was insufficient to establish an injury in fact. But this Court will "rarely" grant a petition for a writ of certiorari "when the asserted error consists of . . . the misapplication of a properly stated rule of law." Sup. Ct. R. 10. And whether a litigant's record evidence is sufficient to demonstrate injury in fact is a "highly fact-specific" question that does not ordinarily warrant this Court's review. *Carney*, 141 S. Ct. at 501.

Seeking to evade the fact-bound nature of the question actually decided by the Federal Circuit, Argentum mischaracterizes the decision below. But this case does not present the questions Argentum offers for review. The Federal Circuit did not "categorically" preclude parties other than the manufacturer or marketer of a generic pharmaceutical from demonstrating Article III standing, nor did the court categorically "reject[ ] the Leahy-Smith America Invents Act's statutory estoppel provisions as a basis to demonstrate injury-in-fact for Article III standing." Pet. i-ii; *see also*, *e.g.*, *id.* at 5 ("The Federal Circuit focused on the fact that KVK will be the manufacturing entity and the entity filing for regulatory approval, which the Federal Circuit deemed to render Argentum's injury not personal."); *id.* at 6 ("[T]he Federal Circuit's decision . . . precludes Argentum from redress on appeal simply because it is in a joint venture."). Rather, the court of appeals held that Argentum offered insuffi-

cient evidence to show injury in fact in the circumstances of this case, including specifically the relationship between Argentum and KVK (both of whom submitted declarations).[4]

Even if this Court were inclined to review whether and when a party dissatisfied by *inter partes* review has Article III standing to appeal, this would be an especially poor vehicle for doing so. Argentum told the Federal Circuit in September 2018 that KVK was likely to submit an ANDA for generic Gilenya® in 8-10 months. Supp. Pet. App. 15a. More than two years later, no ANDA has been filed. Nor is there any evidence in the record showing any concrete steps KVK has taken to develop generic Gilenya® or any specific resources Argentum has devoted to that project. At this point in the litigation, Argentum's evidence of ostensible injury appears to be not just stale but inaccurate.[5]

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[4] The lone amicus suggests that the Federal Circuit has sometimes applied a too narrow version of the doctrine of *competitor* standing. *See* Stroud Br. 8 (complaining that "[a]ll attempts at reliance on the competitor standing have been rebuffed"). Competitor standing was neither pressed nor passed upon below, and is not argued by Argentum in its petition. And just last Term, this Court declined to review the court of appeals' application of that doctrine. *See Gen. Elec. Co.*, 140 S. Ct. 2820. In any event, the amicus brief confirms that the Federal Circuit's standing decisions turn on the evidentiary record submitted in each case. *See* Stroud Br. 13 (noting that in the second *General Electric* case, the court of appeals "took pains to note . . . that it was the additional attorney argument and record evidence that carried the day"). The upshot of the decision below is that Argentum's evidence was factually insufficient.

[5] Even if Argentum or KVK had submitted an ANDA after the Federal Circuit's mandate issued—or were to do so in the future—that would make no difference with respect to Argentum's standing to appeal to the Federal Circuit. Argentum's burden

Argentum had every opportunity to present evidence supporting injury in fact to the Federal Circuit, and the court of appeals made the factual finding that Argentum's two declarations were insufficient to carry its burden. Argentum never grapples with the insufficiency of its own evidence; instead, it makes factual assertions throughout its petition that are not supported by the declarations. Argentum says, for example, that "[i]ts tireless work with KVK has culminated in an affordable, market-ready generic drug from which millions of patients will benefit." Pet. 2. In fact, there is no evidence in the record that Argentum has taken *any* concrete steps to develop a generic version of Gilenya® and, absent the filing of an ANDA and FDA approval, Argentum *cannot* market such a drug. *See* 21 U.S.C. § 355(a); 21 C.F.R. § 314.105(a).[6] Similarly, no evidence supports Argentum's assertions that it will "be subject to an immediate patent infringement suit by Novartis upon the filing of an ANDA," Pet. 3, that the "risk of an infringement suit and the resulting automatic stay block Argentum from market entry," *id.* at 4, or that it "stands to lose significant investment in its joint development of a market-ready generic fingolimod," *id.*[7]

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was to establish the elements of standing as of the time of its appeal; later events cannot confer standing retrospectively. *See Lujan*, 504 U.S. at 570 n.5.

[6] Moreover, there is no evidence that there are "millions" of Gilenya® patients—or even individuals with multiple sclerosis—in the United States. Pet. 2.

[7] Argentum repeats variations of these unsupported assertions throughout its petition. *See*, *e.g.*, Pet. 8 ("Argentum and its manufacturing partner KVK have been working to commercialize an affordable, generic version of Gilenya. This joint venture is ready to bring a generic version to market." (citation omitted)); *id.* at 15 ("The generic version of Gilenya will also be produced

Argentum *argues* that it "is ready and eager to bring a competitive generic to market," Pet. 5, but there is no *evidence* to support that argument. In this respect and others, Argentum makes no effort to engage the Federal Circuit's factual finding that its declarations were insufficient to establish injury in fact. Because that correct finding formed the sole basis for the court of appeals' holding that Argentum lacked standing, this Court should deny review.

Argentum's failure to adduce sufficient evidence to establish Article III standing does not suggest that the Federal Circuit "decided an important question of federal law." Sup. Ct. R. 10(c). To the contrary, Argentum's petition seeks fact-bound error correction in a case where the court of appeals did not err.

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and commercialized from" the manufacturing facilities acquired by KVK); *id.* ("All necessary work to commercialize the generic version of Gilenya has been completed. In other words, Argentum's generic version of Gilenya is market ready subject to FDA approval." (citation omitted)); *id.* ("With its investments and expected revenues approaching $50 million annually, Argentum has a concrete and personal stake in bringing its fingolimod to market free of any encumbrances by the '405 patent and threats of litigation by Novartis."); *id.* at 17 ("Argentum's opposition established that it is not a non-practicing entity.").

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

JANE M. LOVE, PH.D.
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000

MARK A. PERRY
Counsel of Record
JACOB T. SPENCER
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500
MPerry@gibsondunn.com

Counsel for Respondent

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