No. 20-779

IN THE

Supreme Court of the United States

ARGENTUM PHARMACEUTICALS LLC,

Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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PETITIONER'S REPLY

Unable to defend the erroneous standing framework created and applied by the appellate court, Respondent Novartis Pharmaceuticals Corporation's ("Novartis") opposition brief ("Opposition") now instead seeks to distract from the legal issues by miscasting the Federal Circuit's decision as involving merely fact-bound evidentiary rulings that are purportedly not "important to anyone other than" Petitioner Argentum Pharmaceuticals LLC ("Argentum"). Opp. at 16, 21. Novartis's efforts, however, only further highlight its fundamental misapprehensions regarding the issues at hand and perpetuate the Federal Circuit's improperly limiting injury-in-fact analysis for Article III standing.

Contrary to Novartis's assertions, this Petition focuses specifically on the far-reaching implications of the Federal Circuit's decision to categorically deny standing to "an entire class of appellants." Pet. at 6. There is no dispute that joint ventures have become the norm and indeed part of the very fabric of the pharmaceutical industry—allowing companies to combine their respective resources and expertise to bring life-saving treatments to patients. *Id*. at 19. Both smaller generic companies such as Argentum, and larger pharmaceutical giants like Novartis, often enter into such joint ventures. *Id.* at 12-15. While each member of a joint venture may occupy a specific role, all members share stakes in the development, pursuit, benefits, and risks of the venture. The Federal Circuit's decision, however, has drawn a sharp line limiting standing in pharmaceutical patent cases that involve joint ventures to only those members responsible for either manufacturing the drug or seeking regulatory approval.

Novartis's Opposition further confirms that this Court should grant the Petition because the Federal Circuit's decision creates an erroneous legal construct for Article III standing that significantly affects redress of joint venture members throughout the industry. As an initial matter, Novartis *does not dispute* the critical key facts that:

- Novartis has a monopoly over fingolimod treatment of multiple sclerosis based on the '405 patent and the statutory framework for drug approvals by the Food and Drug Administration ("FDA") (Opp. at 3-5);
- Novartis has listed its patent in the FDA's Orange Book as covering its drug Gilenya—providing notice that *any competitor* seeking FDA approval for a generic version will be subject to a patent infringement suit (*id.*);
- Argentum and its joint venture partner KVK-Tech, Inc. ("KVK") must obtain FDA approval for their generic version of Gilenya, and both will be subject to an immediate patent infringement suit by Novartis upon seeking such approval (*id.*);
- Novartis has every incentive to bring suit to maintain exclusivity, including through an automatic 30-months stay during which the FDA cannot approve a generic version and available injunctions (*id.*); and
- Novartis has, in fact, sued for patent infringement *each and every competitor* that has sought FDA approval for a generic version of Gilenya—totaling 20 suits to date against competitors and their subsidiaries or affiliates (Pet. at 10-11).

These undisputed facts were all before the Federal Circuit along with *four sworn declarations*—supported with numerous exhibits—showing that the two joint venture partners Argentum and KVK have invested significantly to develop a generic version of Gilenya, which is market ready. *Id.* at 12-15. The only obstacle is a looming patent infringement suit by Novartis against Argentum as soon as it seeks regulatory approval. *Id.* at 21.

Novartis's Opposition takes the untenable position that the record is speculative and that the four sworn declarations are unsubstantiated.[1] Argentum's declarations and factual representations, however, must be taken as true and all inferences must be drawn in its favor. *See*, *e.g.*, *Warth v. Seldin*, 422 U.S. 490, 501 (1975) ("For purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe [them] in favor of the complaining party."); *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1342 (Fed. Cir. 2020) ("[W]here an appellant seeks review of a final agency action and its standing comes into doubt … we accept as true an appellant's material representations of fact ….") (internal citations and quotation marks omitted).

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[1] Novartis incorrectly argues that two of the declarations are not properly part of the record. Opp. at 8 n.2. It is well-established that "[t]he record on certiorari in the Supreme Court is the *entire record made in the court or courts below*." Moore's Federal Practice § 512.06 (2020) (emphasis added); *see also* Fed. R. App. P. 10(a) ("The following items constitute the record on appeal: (1) the original papers and exhibits filed …."); Sup. Ct. R. 26 ("The record is on file with the Clerk and available to the Justices, and counsel may refer in briefs and in oral argument to relevant portions of the record ….").

The undisputed facts here demonstrate the type of "personal stake in the outcome of the controversy as to assure that concrete adverseness'" for standing. *Massachusetts v. E.P.A.*, 549 U.S. 497, 517 (2007) (citations omitted). After years of investment, Argentum has a personal and concrete stake in obtaining a judgment of invalidity against Novartis's '405 patent—which continues to block Argentum from introducing a generic alternative to Gilenya. And upon seeking FDA approval for its market ready generic version, Argentum faces an imminent and certain infringement suit by Novartis.

Perhaps most telling, the Opposition perpetuates Novartis's refusal to disclaim suing Argentum. The reason is simple. Novartis will indeed sue Argentum upon the filing of an Abbreviated New Drug Application ("ANDA") with the FDA—just as Novartis has done each time a competitor sought FDA approval for a generic alternative to date.

On this record, any court should readily conclude that Argentum has an injury in fact. Pet. at 19-33. The Federal Circuit's categorical denial of standing simply based on Argentum's role in the joint venture is inconsistent with the Constitution and this Court's precedent. *Id.* Moreover, the decision ignores the realities of the pharmaceutical industry in view of the significant contributions and risks borne by each member to a joint venture—even when that member is not responsible for physically manufacturing the drug or submitting the ANDA.

Novartis has failed to refute the basis for this Petition and the enormous ramifications the decision has for any joint venture. And Novartis's arguments regarding statutory estoppel fare no better.

I. Novartis's Opposition Confirms That The Federal Circuit Created And Applied An Erroneous Framework With Far-Reaching Ramifications

Novartis's miscasting of the issues as purely factual ones is belied by its own arguments. To support its assertion that the Federal Circuit's decision turned purely on evidentiary shortcomings, Novartis points to the fact that the Federal Circuit has found standing in other patent cases even though no product had been manufactured yet, and no ANDA had been filed by a pharmaceutical company. Opp. at 4-5 (citing decisions). Specifically, Novartis's cites the decisions in *Altaire* and *JTEKT*. Its reliance on these cases is misplaced. Both cases involved single-actor entities instead of joint ventures.

In *Altaire*, "Altaire [itself] was the company *which intended to file an ANDA*." App. 5a (citation omitted) (emphasis added). The Federal Circuit, in fact, distinguished its analysis here because "[u]nlike in *Altaire*, … any ANDA to be filed 'will be filed by KVK, Argentum's manufacturing and marketing partner.'" *Id.* In doing so, the appellate court drew a sharp line between ANDA filers and non-ANDA filers for the purposes of its injury-in-fact analysis in pharmaceutical patent cases. In other words, the Federal Circuit has arbitrarily held that only the joint venture partner intended to be named as the ANDA filer—here KVK—will have a cognizable injury in fact under Article III. Other joint venture partners—here Argentum—with material interests are precluded from redress simply because they are not the entity filing an ANDA with the FDA. This is inconsistent with the Constitution and this Court's precedent. Pet. at 19-33.

Novartis acknowledges that it can sue both KVK as the actual ANDA applicant for direct infringement, *and* Argentum for indirect infringement. Opp. at 15-16. Novartis, however, opts to simply turn a blind eye to the Federal Circuit's disparate treatment of ANDA and non-ANDA filers in a joint venture for Article III standing—maintaining instead that the issue here is "an evidentiary failure, not a legal rule." *Id.* at 16. Novartis's obstinacy is belied by its own case law and the Federal Circuit's distinctions over that case law—resulting in a new standing construct.

Similarly, *JTEKT* involved a single-actor, fully integrated entity. The court held that the absence of a released "product on the market *at the present time* does not preclude standing" if JTEKT can show that *it* will release a product that "creates a concrete and substantial risk of infringement." *JTEKT Corp. v. GKN Auto. LTD.*, 898 F.3d 1217, 1220-21 (Fed. Cir. 2018) (emphasis added). Here, the court denied standing because *another member of the joint venture* will produce the generic version of Gilenya—purportedly rendering any economic injury "entirely speculative and not personal to Argentum." App. 6a.

If anything, Novartis's Opposition and case law confirms that the Federal Circuit here has created an injury-in-fact standard that categorically precludes redress for injured members of joint ventures in the pharmaceutical industry by limiting Article III standing to only injuries of: (1) the manufacturing partner in the joint venture, and (2) the partner applying for FDA approval in the joint venture. App. 1a-8a. Novartis's attempted deflection to purported evidentiary failures is thus unavailing and demonstrates a fundamental distortion of the issues presented to this Court.

Novartis's Opposition even goes so far as to claim that "Argentum does not attempt to argue that the question presented is important to anyone other than itself." Opp. at 21. Argentum's Petition argues rather extensively that the Federal Circuit's decision "has *enormous ramifications for joint ventures in the pharmaceutical industry*." Pet. at 19 (emphasis added). The thrust of the entire Petition is indeed that the Federal Circuit:

> "slams the door on *any pharmaceutical joint venture partner* seeking to invalidate a patent that blocks market entry, where that partner is not the entity manufacturing the product or submitting the ANDA for FDA approval. This is particularly problematic in industries where, as here, joint ventures between non-manufacturing and manufacturing partners *are very common*. This Court's intervention is, therefore, needed to ensure that Article III is not improperly invoked to eliminate *an entire class of appellants* with a direct financial interest in the outcome of a case and adversely impacted by the results of an adversarial administrative proceeding in which they participated as a party.

Id. at 6 (emphasis added).[2]

The questions presented are indeed paramount to standing for joint ventures at large—especially in the pharmaceutical industry. Novartis's Opposition has not shown otherwise.

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[2] Moreover, Argentum's Petition stands unrebutted on the point that the '405 patent remains a market barrier to all generic competition. *Id.* at 10.

II. Novartis's Factual Arguments Are Also Unavailing

First, Novartis's Opposition fails to refute the argument that Argentum has suffered economic injuries—under this Court's precedent—as a result of Novartis's market barrier. Pet. at 23-27. Novartis instead mischaracterizes Argentum's argument as a novelty or "special exception." Opp. at 18.

But barriers to market entry are precisely the type of particularized and concrete injury that confer Article III standing. Pet. at 23-27 (citing Supreme Court case law). Here, Argentum suffers a legal injury from Novartis' listing of its '405 patent in the Orange Book, which provides notice that any generic competitor is subject to an infringement suit. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007) ("Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch–Waxman Act an ANDA filer … is not legally free to enter the market because federal statutes prohibit it.").

Novartis's '405 patent thus blocks Argentum from any other commercial activities with respect to a generic fingolimod. Ignoring standing based on market barriers, Novartis points to Federal Circuit decisions setting a standard for Article III requirements "that would permit any *inter partes* review petitioner standing to appeal—and this Court has repeatedly denied review of those holdings." Opp. at 18. None of Novartis's cited cases involved the specific joint venture standing issues raised here. That this Court has declined to review other questions does not affect Argentum's Petition.

Novartis also incorrectly argues that Argentum's evidence of an economic injury was too speculative. Opp. at 17-19. Argentum demonstrated through sworn declarations that it contributed significant resources to the joint venture's development and commercialization of a generic alternative to Gilenya. Pet. at 12-15. The two partners share in costs and financial benefits. *Id.* at 13-14. And Argentum is equally responsible for development activities and seeking regulatory approval. *Id.* Notably, all necessary work to commercialize the generic version of Gilenya has been completed. *Id.* at 15. With expected revenues of $50 million annually, Argentum has a concrete and personal stake in bringing its fingolimod product to market free of any encumbrances by the '405 patent and threats of litigation by Novartis. *Id.*

Argentum's sworn declarations must be taken as true and all inferences must be drawn in its favor. *Warth*, 422 U.S. at 501. Novartis cannot simply brush them aside. Nor can Novartis require more specificity. A likely financial loss is sufficient, and no specific accounting is required. *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n.14 (1973) ("We have allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than a fraction of a vote …"); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) ("An allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur.'") (citations omitted).

Second, Novartis misstates several important facts. It argues that Argentum never claimed to face any personal risk of being sued by Novartis. Opp. at

13-14. That is incorrect. *See* CAFC-Appeal 18-2209, ECF 44-1 at 9 ("Argentum possesses a requisite injury that meets the standing requirement … This concrete ANDA-filing plan together with the development efforts KVK and Argentum have already undertaken create a substantial threat of future injury in the form of a near-certain patent infringement suit on the '405 patent."); *id.* at 13 ("Argentum and KVK intend to file an ANDA for a generic version of GILENYA® …."); ECF 88-1 ¶6; CAFC-Appeal 18-2273, ECF 20 at 2-16.

Novartis points out that Argentum has not yet filed its ANDA. Opp. at 15. That only confirms, however, Argentum's injury. Argentum cannot file an ANDA without running the certain risk of being sued by Novartis for infringement of the '405 patent. That is exactly why Argentum challenged the validity of the '405 patent until it was denied standing on appeal by the Federal Circuit. Absent redress, Argentum will continue to be injured. And as Novartis acknowledges, an ANDA is not required for standing. *Id.* at 4-5.

Novartis also asserts that no evidence shows Argentum and KVK had "concrete plans to file an ANDA or had taken any substantive step to prepare any portion of an ANDA." Opp. at 14. Argentum, however, submitted sworn declarations that established all necessary work to commercialize the generic version of Gilenya has been completed. CAFC-Appeal 18-2209, ECF 44-3 ¶¶4-5; *see also* ECF 44-3 ¶¶9-11; ECF 88-2 ¶¶2-3. Novartis cannot simply ignore these sworn declarations. *Supra* n.3. Nor was it proper for the Federal Circuit to ignore these declarations.

Third, Novartis incorrectly argues that third-party or relationship standing cannot exist here because KVK was not hindered from challenging Novartis's '405 patent on its own. Opp. at 16-17. Amongst its responsibilities under the joint venture agreement, Argentum is the sole party representing the interests of the joint venture in patent-related disputes. Pet. at 28. KVK, therefore, has a contractual obstacle to assert the joint venture's rights in this litigation. *Id.*

Moreover, Novartis acknowledged that KVK was listed as a real party in interest. Opp. at 7 n.1. As a "real party in interest" KVK by definition "is a clear beneficiary that has a preexisting, established relationship with the petitioner." *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1366 (2019). On this record, Novartis cannot reasonably deny that there is relationship standing between Argentum and KVK.

III. Novartis's Opposition Fails To Refute Standing Based On Statutory Estoppel

Novartis further incorrectly argues that "Argentum never argued below that it has standing because it was already estopped from bringing further proceedings before the Board." Opp. at 20. Argentum expressly argued this point. CAFC-Appeal 18-2209, ECF 44-1 at 16 ("Under 35 U.S.C. § 315(e)(1)-(2), where the PTAB issues a final written decision in an IPR, the petitioner or real party in interest or privy of the petitioner are estopped *from requesting or maintaining before the PTO* ….'") (emphasis added).

Alternatively, Novartis urges that Argentum could have avoided statutory estoppel simply by

not challenging the '405 patent. Opp. at 20-21. This argument is misplaced and effectively seeks to blame Argentum—the aggrieved party—for challenging an invalid patent that blocks Argentum's market entry and the provision of a more affordable alternative to millions of patients suffering from multiple sclerosis. The issue here is not whether Argentum should have simply abandoned or never pursued market entry. It is rather that the Federal Circuit improperly rejected statutory estoppel as an injury in fact for purposes of Article III standing. Pet. at 33.

Novartis has no other answer or rebuttal. Statutory estoppel has already attached to Argentum. That the decision in *AT&T* involves litigation estoppel rather than statutory estoppel does not change the outcome. Both forms of estoppel prevent bringing future claims. If litigation estoppel is sufficient to constitute an injury in fact for Article III standing, so too is statutory estoppel.

CONCLUSION

For at least the foregoing reasons, the Petition should be granted.

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