No. 18-2273

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Argentum Pharmaceuticals LLC,
Appellant

v.

Novartis Pharmaceuticals Corporation,
Appellee

Appeal from the United States Patent and Trademark Office's Patent Trial and Appeal Board, Case Nos. IPR2017-00854, IPR2017-01550, IPR2017-01929, IPR2017-01946

APPELLANT'S PETITION FOR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

1. Full name of Party Represented by us:	2. Name of any Real Party in Interest not identified in response to Question 3:	3. Parent corporations and publicly held companies that own 10% or more of the stock in the party:
Argentum Pharmaceuticals LLC	KVK-TECH, Inc.	Intelligent Pharma Research LLC APS GP LLC APS GP Investors LLC

4. The names of all law firms and the partners and associates that have appeared for the party now represented by us in the agency or are expected to appear for the party in this court are (and who have not or will not enter an appearance in this case):

Crowell & Moring LLP: Shannon Lentz

Argentum Pharmaceuticals LLC: Tyler Liu

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeals.

Novartis Pharms. Corp. v. Apotex Inc. et al., 18-CV-1038 (D. Del.); *Novartis Pharms. Corp. v. Sun Pharms. Indus., Ltd., et al.*, 18-CV-1040 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, 18-CV-1043 (D. Del.); *Novartis Pharms. Corp. v. Mylan Pharms., Inc.*, 19-CV-00128 (N.D.W.Va); *Novartis Pharms. Corp. v. Mylan Pharms., Inc.*, 19-CV-01118 (D.Del.); *Novartis Pharms. Corp. v. Apotex Inc. et al.*, 20-CV-00133 (D.Del.)

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STATEMENT OF COUNSEL

Based on my professional judgement, I believe the Panel decision is contrary to the following decisions of this Court:

- *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274 (Fed. Cir. 2018)
- *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007)
- *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363 (Fed. Cir. 2019)
- *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076 (Fed. Cir. 2019)

Based on my professional judgment, I believe this appeal requires answering the following precedent-setting question of exceptional importance:

- Whether a partner in a collaboration or joint development venture has Article III standing to appeal an adverse decision where the other partner has Article III standing.

Respectfully submitted,

/s/ Teresa Stanek Rea
TERESA STANEK REA

Counsel of Record for Appellant
Argentum Pharmaceuticals LLC

I. INTRODUCTION

Appellee Novartis Pharmaceuticals Corporation ("Novartis") has been enjoying a significant monopoly—to the tune of approximately $3 billion in annual worldwide sales—with its fingolimod drug Gilenya. Gilenya is covered by Novartis's U.S. Patent No. 9,187,405 (the "'405 patent"), and is used for the treatment of multiple sclerosis. Novartis has been maintaining a firm grip on the market by aggressively enforcing the '405 patent against any generic competitor, effectively blocking market entry of more affordable generic alternatives. According to the Healthcare Bluebook, treating the lifelong condition of multiple sclerosis with Gilenya costs each patient approximately $8,000 a month—totaling a staggering $96,000 every year.

For the past *four years*, Appellant Argentum Pharmaceutical LLC ("Argentum") and its manufacturing partner KVK-Tech Inc. ("KVK") have been working tirelessly to commercialize an affordable, generic version of Gilenya that inures to the benefit of millions suffering from multiple sclerosis. Argentum and KVK have jointly invested significant development resources in this pursuit. Consistent with Novartis's established pattern of enforcing the '405 patent and obtaining injunctions against any generic competitor (*see* Reply Br., 36), Argentum and KVK have been facing the threat of an immediate and inevitable infringement suit once their ANDA for a generic version of Gilenya is filed.

Argentum has been ready to bring its generic to market. The only barrier now to providing an affordable alternative for patients remains the '405 patent. Anticipating that Novartis will follow its pattern of blocking market entry through infringement suits, Argentum has challenged the '405 patent's validity in an *inter partes* review ("IPR") before the Patent Trial and Appeal Board ("Board") and by extension on appeal before this Court. For reasons extensively briefed throughout this appeal, the '405 patent should be held invalid.

After years of investment and litigation, however, a Panel decision has now held Argentum lacks Article III standing because an ANDA was not yet filed and the anticipated applicant was KVK—Argentum's manufacturing partner. The Panel's decision is contrary to this Court's precedent. First, filing an ANDA is not required for standing where the party faces a real and imminent threat of litigation. Here, Argentum has been facing the immediate threat of an induced infringement action based on its joint development with KVK to file an ANDA. Once the ANDA is filed, it is just a matter of time before Novartis will file suit as it has done against all generic competitors. Second, Argentum has standing because it will incur significant economic injury by being blocked from entering the market for 30 months as soon as Novartis files suit. Third, the Panel's decision has drawn an artificial distinction between business partners which will have a chilling effect on innovation and joint ventures.

II. BACKGROUND

Joint development and commercialization of products is common for brand name and generic drug companies alike. Gilenya itself is, in fact, the product of collaborations between Novartis and Mitsubishi Tanabe Pharma Corporation. *See Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1319-1320 (Fed. Cir. 2017); *Novartis AG v. Ezra Ventures, LLC*, No. 4:15-cv-00095, 2015 WL 4197692, at *1 (E.D. Ark. July 10, 2015).

Since its inception, Argentum has engaged in numerous collaborations to develop and successfully commercialize affordable, generic versions of drugs. ECF 44-3 ¶¶3-4. One such collaboration has been with its manufacturing partner KVK. *Id.* ¶¶4-12. Argentum and KVK have been jointly working to develop and commercialize generic versions of multiple drugs, sharing the costs and financial benefits in the process. *Id.* As part of this collaboration, manufacturing facilities totaling over 700,000 square feet have been built out in Pennsylvania. *Id.* ¶¶4-8. Substantial investment has gone into these facilities designed specifically to manufacture generic drugs, including the subject of this dispute—a generic fingolimod form of Gilenya. *Id.*[1]

[1] This is an immunosuppressive drug used to treat multiple sclerosis—a serious disease in which the immune system essentially eats away at the protective covering of nerves leading to progressive decline in motor functionality and even permanent disability. *See* Appx0015-0016. Publicly available data indicates that millions of individuals worldwide suffer from multiple sclerosis each year.

Novartis has maintained a firm monopoly on this drug by enforcing the '405 patent, which remains the sole impediment to market entry. ECF 44-3 ¶¶10-12. Novartis has, in fact, brought over 20 infringement suits against generic companies—such as Argentum—to maintain its market grip on fingolimod drugs used to treat multiple sclerosis. ECF 44 n.1. While facing the threat of an inevitable infringement suit, Argentum and KVK have been jointly working toward filing an ANDA for their fingolimod generic. ECF 44-3 ¶11.

Argentum and four other pharmaceutical companies filed IPR petitions to invalidate the '405 patent. The petitioners jointly appealed the Board's adverse decision. The issues were fully briefed and the Court held oral argument, which was led by Argentum's lead counsel.[2] In its decision, the Panel held that Argentum lacks injury-in-fact for Article III standing. Op. at 3. The Panel found that Argentum has not shown it would bear the risk of any infringement suit lodged by Novartis because KVK—Argentum's manufacturing partner—will be filing the ANDA. *Id.* at 5. The Panel further found that Argentum's partnership with KVK, the sharing of costs, and anticipated profits from the release of a fingolimod generic is insufficient to show economic injury. *Id.* at 6.

[2] Notably, Argentum was joined by other appellants throughout the entire appeal. Novartis does not dispute that at least those other appellants had standing throughout this proceeding. Other than Argentum, all appellants eventually settled with Novartis.

III. REHEARING *EN BANC* IS WARRANTED TO PROPERLY APPLY THIS COURT'S PRECEDENT ON ARTICLE III STANDING

A. The Panel's Decision Incorrectly Narrowed Injury-in-Fact to Threats of Litigation against ANDA Filers

Contrary to this Court's precedent, the Panel held that Argentum lacks Article III standing 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." Op. at 5. This Court has held that a filed ANDA is *not* required for standing on appeal "where there is sufficient evidence that the threat of infringement litigation is an injury that is 'real' and 'imminent.'" *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274, 1283 (Fed. Cir. 2018). In *Altaire*, this Court specifically held that the threat of litigation was real and imminent because appellant "*intends to file* … an ANDA … and it previously has demonstrated its production and marketing capabilities." *Id.* at 1282-1283 (emphasis added).

That is precisely the case here. Argentum has had standing because it faces a real and imminent threat of litigation resulting from its efforts to commercialize a generic version of Novartis's patented drug Gilenya. ECF 44-3 ¶¶4-12. Argentum has developed its generic and has been intending to file an ANDA. *Id.* As this Court held in *Altaire*, "under these circumstances, [the anticipated] injury [from impending litigation] is inevitable." *Altaire*, 889 F.3d at 1283. Applying this Court's precedent, Argentum thus has had standing throughout this appeal.

The Panel's decision nonetheless distinguished *Altaire* on the grounds that here "any ANDA to be filed 'will be filed by KVK, Argentum's manufacturing partner.'" Op. at 5. As an initial matter, both parties will be named on an ANDA even if KVK is listed as the applicant. Once the ANDA is filed, it will be only a matter of time—45 days from notice—before Novartis files suit to retain a 30-month stay against both parties. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

But even if KVK were the only named entity on the ANDA, the Panel incorrectly focused on the threat of *direct* infringement charges faced by an ANDA applicant whilst ignoring induced infringement charges that can be brought against a development partner based on the ANDA filing. Op. at 5. Applying this narrow view, the Court incorrectly held that Argentum had not shown "that *it* would bear the risk of any infringement suit." *Id.* (emphasis added). It is certainly true that filing an ANDA exposes KVK to *direct* infringement charges under 35 U.S.C. § 271(e)(2)(A). Concrete plans to file an ANDA have thus created a substantial risk of a future direct infringement suit by Novartis. *See JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018). The planned ANDA submission, however, has been a culmination of joint development activities between Argentum and KVK. Argentum has been working directly *with* KVK to develop the fingolimod generic, and the two entities have been working together to file the ANDA. ECF 44-3 ¶¶11-12.

Under this Court's precedent, Argentum's joint development efforts give rise to an imminent suit by Novartis against Argentum for *indirect* infringement under 35 U.S.C. § 271(b) predicated on KVK's ANDA filing. *See Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007). In other words, Argentum has had a reasonable apprehension of an induced infringement suit by Novartis once the planned ANDA application had been filed by KVK. In *Forest Labs.*, this Court considered a similar venture between Cipla and Ivax, where only one party was the ANDA applicant. This Court found the inducing partner also liable for infringement and subject to the injunction:

> [W]e do not know if Cipla first approached Ivax or vice versa, but the plan to manufacture, import, market, and sell the EO products described in *the ANDA was undoubtedly a cooperative venture*, and Cipla was to manufacture and sell infringing EO products to Ivax for resale in the United States. Under the standards for inducement which we apply to 35 U.S.C. § 271(b), *Cipla has therefore actively induced the acts of Ivax that will constitute direct infringement upon approval of the ANDA*, and it was thus not inappropriate for the district court to include Cipla within the scope of the injunction. …
>
> [J]ust as Ivax will be liable for, and hence is being enjoined from, the commercial exploitation of escitalopram when it is approved by the FDA and during the life of the patent, so should Cipla be enjoined. *They are partners. Cipla would be contributing to the infringement by Ivax, so the injunction should cover both partners.* It is true that, as the dissent states, § 271(e)(2) defines Ivax's filing of its ANDA as an infringement, and *Cipla did not file the ANDA; however, when the question of an injunction against commercial activity arises, Cipla is as culpable*, and hence entitled to be enjoined, as Ivax.

Id. (emphases added).

The same rationale applies here.[3] Under *Forest Labs.*, Argentum has been at risk of an induced infringement suit by Novartis. Argentum's enterprise with its manufacturing partner KVK has been predicated on the filing of an ANDA so that Argentum can commercialize a fingolimod generic. ECF 44-3 ¶¶4-12. Argentum and KVK have expressly agreed to: (1) "collaborate using their internal resources *to develop and commercialize pharmaceutical products*, including generic drug products"; (2) "prepare, prosecute and defend IPRs and litigation under the Hatch-Waxman Act …"; (3) "*share in external costs*"; and (4) "*share in any financial benefits*." ECF No. 44-3 ¶7 (emphases added).

Given Novartis's pattern of enforcing the '405 patent, a suit against Argentum and KVK is inevitable. Argentum's efforts to invalidate the '405 patent further underscore its apprehension of being sued by Novartis. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) ("Following *MedImmune*, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.").

[3] District courts have consistently applied this Court's precedent for induced infringement based on an ANDA filing. *See, e.g.*, *Shire LLC v. Mylan Inc.*, No. 12-638, 2012 WL 2072665, at *2 (D.N.J. June 7, 2012) ("[T]he Federal Circuit has held that § 271(e) (2) may support an action for induced infringement. … While the filing of an ANDA may be often called a 'technical' act of infringement … [a] party who engages in conduct which actively induces that act of infringement may be sued pursuant to § 271(b).").

Properly applying this Court's precedent, Argentum's immediate risk of suit by Novartis constitutes an injury-in-fact sufficient for Article III standing. *See Altaire*, 889 F.3d at 1282 ("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.'") (emphasis added); *see also Caraco*, 527 F.3d at 1291 (holding that "a reasonable apprehension of suit" is one way of showing an Article III controversy). This risk has existed throughout the entire appeal. The Panel's decision is therefore contrary to this Court's precedent.

B. The Panel's Decision Is Contrary to this Court's Precedent Affording Article III Standing for Economic Injuries Ensuing from Deprivation of Revenues

The Panel's decision also incorrectly dismissed Argentum's Article III standing under the economic injury inquiry. The Panel disagreed that Argentum "will incur significant *economic injury* as its investments in developing a generic version of Gilenya® and preparing an ANDA would be at risk with a 'looming infringement action by Novartis.'" Op. at 5 (emphasis added). In holding that Argentum's injury is "entirely speculative and *not personal to Argentum*" (*id.* at 5-6 (emphasis added)), the Panel improperly ignored this Court's precedent that (1) the "deprivation" of revenue constitutes a concrete and particularized economic injury, and (2) a petitioner has a concrete economic interest in sales of products blocked by a patent holder's listing in the Orange Book.

The Panel reached its conclusion despite the fact that Argentum, pursuant to its joint development agreement with KVK, is entitled to "share in any financial benefits" from the generic version of Gilenya covered by Novartis's '405 patent. *See* Reply Br. at 25; *see also* ECF 44-3 ¶7. The Panel's conclusion is directly at odds with this Court's precedent that deprivation of revenue tied to the validity of a challenged patent constitutes a concrete and particularized economic injury sufficient to confer Article III standing. *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1368 (Fed. Cir. 2019).

In *Samsung*, this Court held that petitioner's status as a member of a patent pool, which included the challenged patent, was indeed enough to confer Article III standing. *Id.* Because the "members who own patents in the pool divide that royalty based on the number of patents in the pool," this Court found that "[m]embers of the pool, like Samsung, therefore stand to gain if another pool patent is invalidated and removed from the pool." *Id.* Because the "deprivation of royalties" was tied directly to the validity of the challenged patent, this Court agreed that Samsung faced a concrete and particularized economic injury if the challenged patent remains valid. *Id.* This Court therefore concluded that the appellant had shown an economic injury that warrants Article III standing to appeal an adverse ruling from an IPR. *Id.*

Under *Samsung*, Argentum has a concrete and particularized economic injury based on the deprivation of expected revenue from its joint development of the fingolimod generic. Just as the petitioner in Samsung, Argentum "stands to gain" from a finding that the '405 patent is invalid. *Id.* Argentum and KVK have been actively working towards filing an ANDA.

While KVK is the manufacturing partner and will be listed as the ANDA applicant, Argentum has been directly involved in the development and is responsible for marketing as well as commercializing the generic. Due to the '405 patent, however, Argentum is currently precluded from selling its already-developed generic. *See* 35 U.S.C. § 271(a). In other words, Argentum is deprived of expected revenues from its joint development efforts in the wake of a real and imminent infringement suit by Novartis. This substantial risk is compounded by an automatic 30-month barrier from market entry after Novartis files its inevitable infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). There can be no dispute that a market barrier would not exist but for the '405 patent and Novartis's consistent enforcement suits. If the '405 patent remains in force, Argentum will be deprived of expected revenues from its development of a competing, generic version. ECF 44-3 ¶¶12 (expected annual revenues of $10-50 million). The Panel's dismissal of this deprivation of revenue as "entirely speculative and not personal to Argentum" (Op. at 5-6) is contrary to this Court's precedent in *Samsung*.

Further, this Court has held that a patentee's listing in the FDA's Orange Book is sufficient to confer Article III standing to an IPR petitioner seeking to launch its generic version. In *Amerigen*, this Court found that the petitioner had "standing to appeal from the Board's decision because the launch of its tentatively approved drug is blocked by the '650 patent, and invalidation of the patent would advance its drug's launch." *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1873 (Fed. Cir. 2019). This Court noted that absent invalidity, "there would be a roughly three-year period" until the patent expired, "during which Amerigen's sales would be blocked by the '650 patent." *Id.* This Court thus concluded Article III was proper because "Amerigen has a concrete, economic interest in the sales of its tentatively approved drug obstructed by the listing of the '650 patent." *Id.* at 1084.

So too here; Gilenya is listed in the FDA's Orange Book as being covered by the '405 patent. ECF 44-3 ¶¶10 n.1. The launch of Argentum's and KVK's jointly-developed fingolimod generic is blocked by the '405 patent, which is not set to expire until 2027. *Id.* Argentum's sales of the fingolimod generic will therefore be blocked for at least *seven years* (four more years than the expiry period in *Amerigen*) unless the patent is invalidated. Invalidating Novartis's patent would enable Argentum and KVK "to launch [their] competing product substantially earlier than [they] otherwise could upon the patent's expiration."

Amerigen, 913 F.3d at 1873. To be clear, Argentum is ready to launch its generic now. Waiting for the '405 patent's expiration would be a significant injury to Argentum—not to mention the public's need for an affordable alternative to Gilenya. Properly applying this Court's precedent in *Amerigen*, it stands to reason that Argentum has a "concrete, economic interest in the sales" of its jointly-developed generic product, and therefore has Article III standing to challenge the Board's adverse decision regarding validity of the '405 patent. *Id.* at 1084.

While it is true that KVK is the anticipated ANDA applicant, it is Argentum's manufacturing partner and both entities will be named on the ANDA. They have been jointly developing the generic and will share profits from sales under their agreement. ECF 44-3 ¶7. In other words, both sides stand to gain and lose equally. Argentum's economic injury from the Board's decision to uphold the challenged patent therefore is and has been at least equivalent to KVK's. And while the petitioner in *Amerigen* had already received tentative approval of its ANDA, Argentum's position is not materially different because it has already developed the generic, is ready to launch it, and has been in the process of filing the ANDA throughout this proceeding.

For at least these reasons, the Panel's decision to reject Argentum's economic injury is also contrary to this Court's precedent, warranting reconsideration and reversal *en banc*.

IV. REHEARING *EN BANC* IS WARRANTED TO ADDRESS THE IMPORTANT ISSUE OF WHETHER A PARTNER IN A JOINT DEVELOPMENT VENTURE HAS ARTICLE III STANDING TO APPEAL AN ADVERSE DECISION

The Panel's decision is not only contrary to this Court's precedent, but also casts a wide net of uncertainty on the availability of appellate redress for entities in joint collaborations and ventures. That is particularly disconcerting to companies in the pharmaceutical industry, in which entities routinely partner to develop and commercialize drugs essential for the treatment of many diseases. It is inconceivable that Article III standing should be construed so narrowly as to exclude one partner in a joint collaboration when both partners share equally in the costs and benefits. Doing so would artificially separate the intertwined rights of entities that share the same "zone of interest."

Here in particular, Argentum and KVK occupy a zone of interest from facing virtually certain infringement suits at the hands of Novartis. As discussed above, Argentum has been facing at least a virtually certain induced infringement action under 35 U.S.C. § 271(b) predicated on its collaborations with KVK to file an ANDA. This is precisely the type of intertwined interests that should confer Article III standing. *Cf. Mylan Pharm. Inc. v. Research Corp. Techs., Inc.*, 914 F.3d 1366, 1373 (Fed. Cir. 2019) (applying the "zone of interest," holding that time-barred IPR petitioners had standing to appeal under 35 U.S.C. § 319).

Leaving the Panel's decision undisturbed will substantially impair innovation through collaborations and risk inhibiting the availability of generic drugs. The Hatch-Waxman legislation struck a careful balance between two competing policy objectives: (1) inducing innovators to make the investments necessary to develop new drugs, and (2) enabling generics to bring lower-cost versions of those drugs to market in a timely fashion. *See Teva Pharm Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

The decision by the Panel upsets this balance. Collaboration by innovator companies is encouraged. The standing issue places any collaboration by a generic drug company at a significant disadvantage because they may lose the right to appeal an adverse decision. To deny Article III standing to a company developing a generic drug simply because its partner may file the ANDA does not appreciate the varied contributions of each collaborator, resulting in a chilling effect for joint ventures in the development of generic drugs. The ensuing risks for a company wanting to develop a generic product but unable to defend its rights at the appellate level is untenable. This Court should therefore hold that all partners to a joint venture have equal standing.

V. CONCLUSION

For the foregoing reasons, Appellant Argentum Pharmaceutical LLC respectfully submits that the Panel's decision is contrary to this Court's precedent. Properly applying this Court's precedent *en banc*, the panel's decision should be reversed and the matter should be remanded to the panel for a decision on the merits.

Respectfully submitted,

DATED: June 8, 2020

/s/ Teresa Stanek Rea

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **APPELLANT'S PETITION FOR REHEARING *EN BANC*** was caused to be served on June 8, 2020 on all counsel of record by the CM/ECF system.

DATED: June 8, 2020

/s/ April Marconi
April Marconi
Case Manager

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this petition complies with the type-volume limitation of Fed. R. App. P. 35(b)(2).

1. Exclusive of the exempted portions of the petition, as provided in Fed. Cir. Rule 35(c)(2), the petition contains 3,833 words.

2. The petition has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Deborah Yellin
Deborah Yellin

ADDENDUM

United States Court of Appeals for the Federal Circuit

ARGENTUM PHARMACEUTICALS LLC,
Appellant

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Appellee

2018-2273

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-00854, IPR2017-01550, IPR2017-01929, IPR2017-01946.

Decided: April 23, 2020

TERESA STANEK REA, Crowell & Moring, LLP, Washington, DC, argued for appellant. Also represented by DEBORAH YELLIN.

JANE M. LOVE, Gibson, Dunn & Crutcher LLP, New York, NY, argued for appellee. Also represented by ROBERT TRENCHARD.

Before LOURIE, MOORE, and REYNA, *Circuit Judges*.

MOORE, *Circuit Judge*.

On February 3, 2017, Apotex Inc. and Apotex Corp. (collectively, Apotex) filed a petition for *inter partes* review of Novartis Pharmaceuticals Corporation's U.S. Patent No. 9,187,405. The Board instituted proceedings on July 18, 2017, and granted Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE's (collectively, Sun); Teva Pharmaceuticals USA, Inc. and Actavis Elizabeth LLC's; and Argentum Pharmaceuticals LLC's requests for joinder under 35 U.S.C. § 315(c). After institution, Patent Owner, Novartis, filed a contingent motion to amend. On July 11, 2018, the Board concluded that Apotex, Sun, Teva, Actavis, and Argentum (collectively, Petitioners) had not demonstrated unpatentability of the claims and denied the motion to amend as moot. Petitioners appealed the Board's findings. During the appeal process, all Petitioners other than Argentum settled their respective appeal with Novartis.[1]

On August 29, 2018, before opening briefs had been filed, Novartis filed a motion to dismiss Argentum's appeal for lack of standing. Argentum opposed the motion on September 10, 2018, and included declarations of Jeffrey Gardner, Argentum's CEO, and Anthony Tabasso, President and CEO of KVK-Tech, Inc., Argentum's manufacturing and marketing partner. We directed Argentum and Novartis to address Argentum's standing in their briefs, which they did. Initially, Argentum argued that we need not reach the issue of its standing because only one party must have standing for an action to proceed in an Article III Court, and "the other seven appellants undisputedly have standing." Appellant's Br. viii. Following the settlement

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[1] Teva, Actavis, and Sun settled before argument and Appeal Nos. 18-2260 (Teva and Actavis) and 18-2230 (Sun) were dismissed, respectively. Apotex settled after argument and Appeal No. 18-2209 was dismissed.

of all parties other than Argentum, Novartis submitted a notice of supplemental authority under Federal Rule of Appellate Procedure 28(j) stating that "now that Argentum is the only appellant, Article III standing has become a threshold issue" and that we must assess our "jurisdiction under Article III of the Constitution before addressing the merits of the case." D.I. 131 at 2 (citing *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1171 (Fed. Cir. 2017)).[2]

Because we hold that Argentum lacks Article III standing, we dismiss the appeal and do not reach the merits of the Board's ruling on the claims of the '405 patent.

DISCUSSION

"Although we have jurisdiction to review final decisions of the Board under 28 U.S.C. § 1295(a)(4)(A), 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. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). This holds true "even if there is no such requirement in order to appear before the administrative agency being reviewed." *Id.* (citing *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014)). To prove standing, Argentum bears the burden of showing that it has "(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). Argentum must "'supply the requisite proof of an injury in fact when it seeks review of an agency's final action in a federal court,' by creating a necessary record in this court, if the record before the Board does not establish standing." *JTEKT Corp. v. GKN Automotive LTD.*, 898 F.3d 1217,

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[2] All citations to the court's docket are to *Apotex Inc. v. Novartis Pharmaceuticals Corp.*, Appeal No. 2018-2209.

1220 (Fed Cir. 2018) (quoting *Phigenix, Inc.*, 845 F.3d at 1171–72). "To 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). An injury is particularized if it "affect[s] the [appellant] in a personal and individual way." *Lujan*, 504 U.S. at 560 n.1.

Argentum argues that it demonstrated at least three concrete injuries in fact. First, Argentum argues that without an opportunity to seek this Court's redress, it faces a real and imminent threat of litigation as it jointly pursues, along with its partner KVK-Tech, Inc., a generic version of Novartis' Gilenya® product for which they are in the process of filing an ANDA. It argues that given that Novartis already sued multiple generic companies to protect Gilenya®, "it is virtually certain that Novartis will sue Argentum and KVK," which is "far from conjectural" and "constitutes an imminent injury for purposes of standing." Appellant's Reply Br. 28.

Novartis argues that any ANDA to be filed for a generic version of Gilenya® "will be filed by KVK, Argentum's manufacturing and marketing partner" (*see* D.I. 44-3 (Gardner Dec.) ¶ 11), and thus KVK, not Argentum is at risk of being sued. And even if the litigation were personal to Argentum, it would not confer standing because it is merely conjectural. Appellee's Br. 39 (citing *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1367 (Fed. Cir. 2019) (concluding that appellant did not "sufficiently allege[] current or nonspeculative activities of its own that arguably fall within the scope of the upheld claims" to amount to harm to it)). It argues that there is no evidence of "concrete plans for future activity that creates a substantial risk of future infringement or [will] likely cause the patentee to assert a claim of infringement." Appellee's Br. 39 (quoting *JTEKT Corp.*, 898 F.3d at 1221).

Citing our decision in *Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, Inc.*, Argentum responds that "showing a concrete injury-in-fact does not necessitate an already-filed ANDA." Appellant's Reply Br. 27 (citing 889 F.3d 1274, 1282–83 (Fed. Cir. 2018), *remand order modified by stipulation*, 738 F. App'x 1017 (Fed. Cir. 2018)). Argentum's contentions are unavailing. In *Altaire*, Altaire was the company which intended to file an ANDA and would be at imminent risk of being sued. We held that Altaire had standing because the threat of litigation was "real" and "imminent" and Altaire was affected "in a personal and individual way." *See Altaire*, 889 F.3d at 1282–83; *see also General Electric Co. v. United Techs. Corp.*, 928 F.3d 1349, 1353–54 (Fed. Cir. 2019) (determining there was no "concrete and imminent injury to GE," and that GE asserted "only speculative harm"). Unlike in *Altaire*, according to Mr. Gardner, any ANDA to be filed "will be filed by KVK, Argentum's manufacturing and marketing partner." D.I. 44-3 (Gardner Dec.) ¶ 11. And Mr. Gardner stated that "Novartis will inevitably sue Argentum's manufacturing and marketing partner KVK for patent infringement upon KVK's filing an ANDA for a generic version of GILENYA® . . . ." *Id.* ¶ 14; *see also id.* ¶ 15. No 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. *See, e.g.*, *id.* ¶ 11.

Second, Argentum argues that it will incur significant economic injury as its investments in developing a generic version of Gilenya® and preparing an ANDA would be at risk with a "looming infringement action by Novartis." Appellant's Br. 49. Specifically, it asserts that it will suffer at least $10–50 million per year in lost profits once the FDA grants provisional approval to the ANDA. Appellant's Reply Br. 28–29 (citing D.I. 44–3 (Gardner Dec.) ¶ 12). Novartis argues that Argentum's alleged "economic injury," which is entirely speculative and not personal to

Argentum, does not suffice to establish injury in fact because it is not concrete or particularized.

Argentum has not provided sufficient evidence to establish an injury in fact through economic harm. *General Electric*, 928 F.3d at 1354–55 (rejecting GE's economic loss allegation of increased research and development costs where GE failed to provide details such as "an accounting for the additional research and development costs expended" or "evidence that GE actually designed a [product covered by the upheld claims]"). Argentum's or KVK's purported investments include KVK's renovation of manufacturing facilities that "KVK intends to use . . . to manufacture drugs developed through its joint collaboration with Argentum." D.I. 44–2 (Tabasso Dec) ¶ 4. However, Mr. Tabasso specifically states that "[t]he generic version of PAZEO®," a drug unrelated to the patent at issue, "will be produced in KVK's new manufacturing space which will come online in the next year." *Id.* And Mr. Gardner declared that "Argentum has partnered with KVK . . . to develop generic versions of multiple generic drug products" without providing evidence specific to a generic Gilenya® product. *See* D.I. 44-3 (Gardner Dec.) ¶ 4; *see also id.* ¶ 6.

Argentum likewise has failed to provide sufficient evidence that it invested in KVK's generic Gilenya® product or ANDA. It stated only in generalities that both "KVK and Argentum have been diligent in working toward FDA submission of the ANDA" and that "Argentum has invested significant man-power and resources to the endeavor." D.I. 44-3 (Gardner Dec.) ¶ 11; *see also id.* ¶ 8 (stating that "[e]xternal costs are shared by Argentum and KVK on an opportunity-by-opportunity basis"); *id.* ¶ 9 (generally stating that "[a] number of products are currently being jointly developed by Argentum and KVK" but listing an unrelated generic product). And its assertion that it will suffer at least $10–50 million per year in lost profits once the FDA grants provisional approval to the ANDA is both conclusory

and speculative. *See* Appellant's Reply Br. 28 (citing D.I. 44-3 (Gardner Dec.) ¶ 12). This cannot suffice to establish an injury in fact 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).

Third, Argentum argues 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 future infringement action. Novartis argues that Argentum has not shown that it will be harmed by estoppel where it has not established there is risk of an infringement suit. Appellee's Br. 42–43 (citing *JTEKT Corp.*, 898 F.3d at 1221). As the court stated in *AVX*, "we have already rejected invocation of the estoppel provision as a sufficient basis for standing." 923 F.3d at 1362–63 (citing *Phigenix*, 845 F.3d at 1175–76 ("§ 315(e) do[es] not constitute an injury in fact when, as here, the appellant is not engaged in any activity that would give rise to a possible infringement suit.") (alteration in original) (internal quotations omitted)); *see also JTEKT*, 898 F.3d at 1221; *General Electric*, 928 F.3d at 1355. Accordingly, we hold that Argentum has failed to prove that it has suffered an injury in fact necessary to establish standing.

CONCLUSION

We have considered the parties' remaining arguments and do not find them persuasive. Because Argentum failed to establish an injury sufficient to confer Article III standing, we dismiss the appeal.

DISMISSED

COSTS

Costs to Novartis.