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.