NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PFIZER INC.,
Appellant

v.

CHUGAI PHARMACEUTICAL CO., LTD.,
Appellee

2019-1513, 2019-1514

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-01357, IPR2017-01358.

Decided: April 27, 2020

JOHN P. SCHEIBELER, White & Case LLP, New York, NY, argued for appellant. Also represented by DIMITRIOS T. DRIVAS, DANIEL LEDESMA, NICOLE LIEBERMAN, CATALIN SEBASTIAN ZONTE; ELIZABETH K. CHANG, Palo Alto, CA.

JON STEVEN BAUGHMAN, Paul, Weiss, Rifkind, Wharton & Garrison LLP, Washington, DC, argued for appellee. Also represented by MEGAN FREELAND RAYMOND.

Before PROST, *Chief Judge,* BRYSON and DYK, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Chugai Pharmaceutical Co., Ltd., owns U.S. Patent Nos. 7,332,289 ("the '289 patent") and 7,927,815 ("the '815 patent"). In two inter partes review proceedings, Pfizer Inc. petitioned the Patent Trial and Appeal Board to invalidate most of the claims of the '289 and '815 patents. In each IPR, the Board held that Pfizer did not prove that any of the challenged claims were unpatentable, and Pfizer appealed. Because Pfizer has failed to establish that it has Article III standing for purposes of the proceedings before this court, we dismiss both appeals.

I

The '289 patent and the '815 patent share a common specification. The patents describe methods for purifying proteins by "removing contaminant DNA from a sample containing a physiologically active protein." '289 patent, col. 1, ll. 5–8. According to the patents, the inventors "made the surprising finding that contaminant DNA can be efficiently removed from a sample containing a physiologically active protein without using complicated chromatographic processes . . . ." *Id.* at col. 1, ll. 59–62.

Pfizer petitioned for inter partes review of claims 1–8 and 13 of the '289 patent and claims 1–7, 12, and 13 of the '815 patent. The Board instituted inter partes review of all the challenged claims on all the grounds that were asserted. In its final written decisions, however, the Board held that Pfizer had not proved that any challenged claim was unpatentable. Pfizer appealed, asserting that we have jurisdiction under 35 U.S.C. § 141 and 28 U.S.C. § 1295(a)(4)(A).

II

Any person or entity may petition the Patent and Trademark Office to institute an IPR proceeding, even if they do not have Article III standing. *JTEKT Corp. v. GKN Auto. LTD.*, 898 F.3d 1217, 1219 (Fed. Cir. 2018); *Fisher & Paykel Healthcare Ltd. v. ResMed Ltd.*, 789 F. App'x 877, 878 (Fed. Cir. 2019). A party that appeals to this court from a decision of the Board, however, must have Article III standing in order for this court to consider the merits of the appeal. *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014); *JTEKT*, 898 F.3d at 1219.

To establish Article III standing, an appellant must show 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). "That said, where Congress has accorded a procedural right to a litigant, such as the right to appeal an administrative decision, certain requirements of standing—namely immediacy and redressability, as well as prudential aspects that are not part of Article III—may be relaxed." *Consumer Watchdog*, 753 F.3d at 1261 (citing *Massachusetts v. EPA,* 549 U.S. 497, 517–18 (2007)). Nonetheless, a "party invoking federal jurisdiction must have 'a personal stake in the outcome'" in order to meet the injury in fact requirement. *Consumer Watchdog*, 753 F.3d at 1261 (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983)).

"To qualify as a case fit for federal-court adjudication, 'an actual controversy must be extant at all stages of review . . . .'" *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (quoting *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975)); *see also Momenta Pharm., Inc. v. Bristol-Myers Squibb Co.*, 915 F.3d 764, 770 (Fed. Cir. 2019) (noting that standing requires that the requisite personal

interest "exist at the time of commencement of the litigation"); *Vanda Pharm. Inc. v. W. Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018). In order to demonstrate the requisite injury in fact in an IPR appeal where the appellant is not currently engaging in infringing activity, the appellant typically must show that it has concrete plans for future activity that creates a substantial risk of future infringement or would likely cause the patentee to assert a claim of infringement. *JTEKT*, 898 F.3d at 1220; *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1005 (Fed. Cir. 2018).

As the party seeking judicial review, Pfizer bears the burden of establishing standing. See *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1171 (Fed. Cir. 2017). An appellant 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*, 898 F.3d at 1220 (quoting *Phigenix*, 845 F.3d at 1171–72). "When the record before the Board is inadequate," an appellant "'must supplement the record to the extent necessary to explain and substantiate its entitlement to judicial review,' such as by submitting 'affidavits or other evidence to demonstrate its standing.'" *JTEKT*, 898 F.3d at 1220 (quoting *Phigenix*, 845 F.3d at 1173).

Pfizer has not established that it had suffered a concrete and particularized injury in fact at the beginning of this appeal. Pfizer contends that its purported injury in fact stems from Pfizer's launch of its product Ruxience® in January 2020. Ruxience® is a biosimilar product to a rituximab drug made by Genentech, a competitor of Pfizer. Pfizer contends that Genentech is a wholly owned subsidiary of the Roche Group and that F. Hoffmann-La Roche Ltd is the majority owner of appellee, Chugai. Pfizer entered into a settlement agreement with Genentech that authorized Pfizer to begin selling its biosimilar rituximab drug in January 2020. Chugai was not a party to that settlement

agreement, and Pfizer did not get a license from Chugai for the patents at issue in this appeal. Pfizer suggests that Chugai is likely to accuse Pfizer's rituximab biosimilar product of infringing the patents at issue in this appeal because Pfizer's biosimilar uses Protein A chromatography, and because the patents "concern methods of purifying proteins involving the use of protein A chromatography."

Although Pfizer suggests that Chugai is likely to assert a claim of infringement, Pfizer did not address in its briefing or supplemental evidence when that risk arose. Pfizer filed its notice of appeal on January 30, 2019, and the appeal was docketed several days later. But the only evidence of standing that Pfizer has provided to this court relates to events that occurred much later in 2019. Specifically, Pfizer submitted evidence that the FDA approved its rituximab biosimilar in July 2019 and that Pfizer announced at the end of October 2019 that it would begin selling the biosimilar in the United States in January 2020. Pfizer did not, however, cite any evidence regarding its activities or plans relating to its rituximab biosimilar before July 2019. Pfizer thus failed to supply any evidence that it was suffering from an injury in fact when this appeal began. Nor has Pfizer offered evidence that would allow us to evaluate whether it practices or intends to practice the patented methods in the course of making its biosimilar product. *See Fisher*, 789 F. App'x at 878 ("Fisher has not provided any, let alone sufficient, detail regarding features of its future products to enable us to determine that its activities create a substantial risk of future infringement of the '556 patent. Absent such a showing, Fisher cannot establish standing to maintain this appeal, and this court lacks authority to consider the merits.").

At oral argument, Pfizer's counsel said that it was "self-evident to the parties" that there was "a product at issue" when the appeal began. Oral Argument at 4:00**.** It is not self-evident to the court, however, that there was standing at the outset of the appeal, or even later. It was Pfizer's

responsibility to submit evidence to make its standing evident to the court, which it failed to do.

It appears that Pfizer's "self-evident" theory stems from the fact that Pfizer listed "rituximabIPR@winston.com" in its petitions as its service email address for the IPR proceedings. Chugai, in turn, listed Genentech, Inc., as a potential real party in interest in the IPR proceedings and subsequent appeals because Genentech sells a rituximab product and Pfizer's service email suggested that Pfizer believed the litigation related to rituximab. But Pfizer's service email address and Chugai's response do not tell the court anything useful about Pfizer's plans for its biosimilar, Ruxience®, as of the beginning of 2019, when this appeal began. Nor does that evidence establish with sufficient likelihood that the processes used to prepare Pfizer's product would infringe Chugai's patents. The court will therefore not find standing based on that evidence.

Pfizer also contends that the statutory estoppel effect of 35 U.S.C. § 315(e) "enhances Pfizer's stake in the outcome of this case." But the estoppel provision does not constitute an injury in fact when, as here, there is no evidence that the appellant was or is engaged in any activity that would give rise to a possible infringement suit. *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1362–63 (Fed. Cir. 2019); *Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1355 (Fed. Cir. 2019); *Argentum Pharm. v. Novartis Pharm. Corp.*, Case No. 2018-2273 (Fed. Cir. Apr. 23, 2020).

Because Pfizer has failed to establish that it was suffering a cognizable injury at all stages of these appeals sufficient to give Pfizer Article III standing to seek relief in this court, we dismiss the appeals.

No costs.

DISMISSED