United States Court of Appeals for the Federal Circuit

MOMENTA PHARMACEUTICALS, INC.,
Appellant

v.

BRISTOL-MYERS SQUIBB COMPANY,
Appellee

2017-1694

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-01537.

Decided: February 7, 2019

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for appellant. Also represented by SETH W. LLOYD, BRIAN ROBERT MATSUI, JOSEPH R. PALMORE; BRIAN M. KRAMER, San Diego, CA.

CHRISTOPHER NEIL SIPES, Covington & Burling LLP, Washington, DC, argued for appellee. Also represented by BRADLEY KEITH ERVIN, MEGAN PATRICIA KEANE, GEORGE FRANK PAPPAS.

WILLIAM BARNETT SCHULTZ, Zuckerman Spaeder LLP, Washington, DC, for amicus curiae Association for

Accessible Medicines. Also represented by CARLOS T. ANGULO, JEREMY KREISBERG.

BRIAN MATTHEW BOYNTON, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, for amici curiae Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization. Also represented by CHRISTOPHER ASTA, THOMAS SAUNDERS.

Before NEWMAN, DYK, and CHEN, *Circuit Judges*.

NEWMAN, *Circuit Judge*.

Momenta Pharmaceuticals, Inc. ("Momenta") appeals the decision of the Patent Trial and Appeal Board ("PTAB" or "Board") sustaining patentability of claims 1 through 15 (all the claims) of United States Patent No. 8,476,239 ("the '239 Patent") owned by Bristol-Myers Squibb Company ("BMS").[1] The appeal is dismissed for absence of standing/jurisdiction and for mootness.[2]

BACKGROUND

The '239 Patent, entitled "Stable Protein Formulations," describes and claims specific fluid formulations of the protein molecule CTLA4Ig (cytotoxic T-lymphocyte associated protein 4 immunoglobulin), an immunosuppressive agent used in treatment of immune system disorders such as rheumatoid arthritis. The product has the common name "abatacept" and the BMS brand name Orencia®.

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[1] *Momenta Pharm., Inc. v. Bristol-Myers Squibb Co.*, 2016 WL 7987985 (P.T.A.B. Dec. 22, 2016).

[2] Momenta's unopposed Motion to amend Protective Order (Dkt. 101), filed Nov. 2, 2018, is granted. BMS's unopposed Motion to Supplement the Record on Standing (Dkt. 90-1), filed Nov. 11, 2017, is granted.

Momenta in July 2015 petitioned the United States Patent & Trademark Office ("PTO") for Inter Partes Review of the '239 Patent, in accordance with the post-grant review provisions of the America Invents Act, codified at 35 U.S.C. § 311 et seq. At that time Momenta was reportedly attempting to develop a biosimilar counterpart of Orencia®. The PTAB instituted review, conducted trial, and sustained patentability of the '239 Patent claims.

Momenta filed an appeal to the Federal Circuit, as provided by 35 U.S.C. § 319:

> 35 U.S.C. § 319. **Appeal**
>
> A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 [appeal to the Federal Circuit] through 144. Any party to the inter partes review shall have the right to be a party to the appeal.

BMS moved to dismiss the appeal, stating that Momenta does not have standing to invoke federal court jurisdiction, citing the constitutional requirements of Article III. BMS stated that Momenta's proposed product had failed its Phase 1 clinical trials and had been withdrawn.

Momenta responded that it had not abandoned its intent to produce a counterpart of the Orencia® product, that the '239 Patent is an obstacle to these activities, and that it is injured by the estoppel provision, 35 U.S.C. § 315(e). Momenta stated that this appeal meets the criteria of Article III, citing the "relaxed" standard for Article III compliance when the right of appeal is established by statute. We duly heard argument on the motion to dismiss and on the merits of the appeal, and took the case under submission.

On October 1, 2018, Momenta filed a Letter under Fed. R. App. P. 28(j), enclosing a press release captioned "Momenta Pharmaceuticals Completes Strategic Review to

Refocus its Operations and Drive Shareholder Value." (Dkt. 98). The press release announced "the completion of its strategic review aimed at reducing costs of biosimilar development," and that "[t]he Company has initiated discussions with its collaboration partner, Mylan, to exit its participation in the development of its other five biosimilar programs including M834, a proposed biosimilar to ORENCIA®, and intends to focus solely on the continued development of M710 [proposed biosimilar to EYLEA®]." Press release, at 1. Momenta's Letter stated that it "will promptly inform the Court of any outcome of its discussions with Mylan that might affect this Court's ongoing jurisdiction." Letter, at 1. BMS responded that this information confirms Momenta's lack of standing to appeal. (Dkt. 99).

Momenta did not further communicate to the court, and on October 23, 2018 we issued an Order to Show Cause why the appeal should not be dismissed as moot. (Dkt. 100). Momenta responded on November 2, 2018, stating that the appeal was not moot because:

> As of today, the companies continue to be jointly responsible under that agreement for product development and for sharing the costs of that development, which are substantial. And because of BMS's patent and the Board's decision upholding it, Momenta and its partner Mylan still face the same fork in the road about the commercial formulation for their biosimilar product—they must decide whether to proceed with the current formulation or switch to a more expensive and potentially less commercially viable option. That decision and the costs associated with it still turn on the outcome of this appeal.

Momenta Response to Order to Show Cause, at 2–3 (Dkt. 102). Momenta included a Declaration of its Chief Business Officer, Young Kwon, who declared that "[t]he parties have not yet reached an understanding about whether or

when any termination notice will be delivered," Declaration, ¶5, and recited Momenta's economic interest in any Orencia® biosimilar that might be developed by Mylan, and Momenta's potential right to royalties from Mylan should this product be developed by Mylan. *Id*. at ¶6.

BMS responded that a third party's possible future development of this abandoned product does not provide constitutional standing to Momenta. BMS stated that Momenta's "possible future royalty . . . is too speculative to support standing," BMS Response to Order to Show Cause, at 7, November 13, 2018 (Dkt. 104), and that "hypothetical future harm falls short of the 'certainly impending' injury-in-fact required by Article III." BMS Letter, at 1, October 3, 2018 (Dkt. 99) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 402 (2013)). In *Clapper* the Court stated that "we have repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,' and that '[a]llegations of *possible* future injury' are not sufficient." 568 U.S. at 409 (emphases original) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

On December 10, 2018 BMS filed another Letter under Rule 28(j), enclosing a Preliminary Prospectus Supplement and a Form 8-K that Momenta had filed with the Securities and Exchange Commission on December 6, 2018. These documents state:

> We have elected to terminate our collaboration agreement with Mylan with respect to the development of . . . M834, a proposed biosimilar to ORENCIA® . . . . On November 19, 2018, we delivered a formal notice of this partial termination to Mylan, as provided in the collaboration agreement.

Preliminary Prospectus Supplement at S-2; Form 8-K at 3. (Dkt. 105). BMS states that these documents confirm Momenta's lack of or loss of standing, and establish that the appeal is moot. Momenta has not responded, and has not withdrawn its appeal.

DISCUSSION

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341–42 (2006) (quoting *Raines v. Byrd,* 521 U.S. 811, 818 (1997)).

Precedent has distinguished the standards for statutorily authorized appeals of decisions of administrative agencies, compared with the jurisdictional standards for bringing a declaratory action directly in federal court. The Court stated in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992):

> The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy.

Id. at 572 n.7; *see also Massachusetts v. E.P.A.*, 549 U.S. 497, 517–18 (2007). The Court stated that Congress may "elevat[e] to the status of legally cognizable injuries concrete, *de facto* injuries that were previously inadequate in law." *Lujan*, 504 U.S. at 578. However, the appellant must always have a "concrete and particularized" interest in the outcome – an interest, to the extent one existed, that has now been eliminated by Momenta. *Id.* at 560.

The Court in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009) elaborated that although the criteria of immediacy and redressability may be relaxed on appropriate facts, "[u]nlike redressability, however, the requirement of injury in fact is a hard floor of Article III jurisdiction that cannot be removed by statute." *Id.* at 497. The Court reiterated that "Article III standing requires a concrete injury even in the context of a statutory violation." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016).

It is established that the "'case' and 'controversy' restrictions for standing do not apply to matters before administrative agencies and boards, such as the PTO," *Ritchie v. Simpson*, 170 F.3d 1092, 1094 (Fed. Cir. 1999). The Court recognized that "[p]arties that initiate the [Inter Partes Review] proceeding need not have a concrete stake in the outcome; indeed, they may lack constitutional standing." *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016).

Although the statutory grant of judicial review may "relax" the Article III criteria, judicial review of agency action remains subject to the constitutional foundation of injury-in-fact, lest the court occupy only an advisory role. *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014); *see also Raines*, 521 U.S. at 820 n.3 ("Congress cannot erase Article III's standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing." (citing *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 100 (1979))); *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975) ("[A] federal court has neither the power to render advisory opinions nor to decide questions that cannot affect the rights of litigants in the case before them." (internal citation and quotation marks omitted)).

Although Momenta had initially stressed that it had spent millions of dollars in its development of an Orencia® biosimilar, now upon Momenta's termination of all potentially infringing activity, Momenta has not shown "an invasion of a legally protected interest" that is "actual or imminent, not conjectural or hypothetical." *See Lujan*, 504 U.S. at 560. On abandoning development of this product, Momenta has no legally protected interest in the validity of the '239 Patent, and there is no "real need to exercise the

power of judicial review." *Warth v. Seldin*, 422 U.S. 490, 508 (1975).[3]

Momenta argues that since the purpose of the America Invents Act is to provide an alternative to district court litigation, appeal should be available from the PTAB as it would be available from a district court decision. Momenta states that the estoppel provision provides injury-in-fact, and that this suffices to support constitutional standing. However, estoppel of Momenta is irrelevant now that Momenta has "exited" its development of the Orencia® product. Estoppel cannot constitute an injury-in-fact when Momenta "is not engaged in any activity that would give rise to a possible infringement suit." *Consumer Watchdog*, 753 F.3d at 1262; *see also Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013) (the party must be in the position of "seek[ing] a remedy for a personal and tangible harm"); *Gill v. Whitford*, 138 S. Ct. 1916, 1929 (2018) ("the requirement of such a personal stake [in the outcome] 'ensures that courts exercise power that is judicial in nature'" (quoting *Lance v. Coffman*, 549 U.S. 437, 441 (2007))).

Momenta's argument that it might at some future time receive a royalty from Mylan, if Mylan should produce an Orencia® biosimilar, has no support in precedent. *See Clapper*, 568 U.S. at 414 n.5 (To establish Article III standing, "[p]laintiffs cannot rely on speculation about the

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[3] The legislative record on enactment of the America Invents Act, *e.g.,* H.R. Rep. No. 112-98, pt. 1 (2011) at 45-47, suggests that judicial review was explicitly provided in *inter partes* reexamination and then in *inter partes* review because the limitation on the right to appeal from *ex parte* reexamination had "proved to make it a less viable alternative . . . than Congress intended." *Id.* at 45. However, the legislative record does not suggest a congressional intent to adjust the application of Article III to PTAB appeals.

unfettered choices made by independent actors not before the court." (internal quotation marks and citation omitted)); *United Transp. Union v. ICC*, 891 F.2d 908, 912 (D.C. Cir. 1989) ("[F]or standing purposes, we may reject as overly speculative those links which are predictions of future events (especially future actions to be taken by third parties).").

The Federal Circuit has applied these principles to varied facts in several America Invents Act appeals from PTAB decisions. In *Consumer Watchdog* the court held that a general public interest without a particularized or personal interest and injury does not provide standing to appeal a decision of the PTAB. 753 F.3d at 1262–63. In *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1173–76 (Fed. Cir. 2017), the court held that Phigenix did not achieve standing based on Phigenix's assertion of a possible future economic interest.

In *RPX Corp. v. ChanBond LLC*, No. 17–2346, ECF 39 (Fed. Cir. Jan. 17, 2018), the court held there was not standing to appeal because it was "undisputed that RPX is not engaged in any potentially infringing activity regarding the '822 patent." *Id.* at *5. In *JTEKT Corp. v. GKN Automotive Ltd.*, the court opined that there may be circumstances in which a PTAB petitioner "has no product on the market at the present time" yet "does not preclude Article III standing," provided that the petitioner has "concrete plans for future activity that creates a substantial risk of future infringement." 898 F.3d 1217, 1220–21 (Fed. Cir. 2018) (citing *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274, 1280–83 (Fed. Cir. 2018), *remand order modified by stipulation*, 738 F. App'x 1017 (Fed. Cir. 2018)).

In *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1005 (Fed. Cir. 2018), the court held that appeal was available because the parties were direct competitors and were in commercial dispute, and the petitioners faced

a significant risk of patent infringement in their demonstration plant that was entering into operation. The court determined that the actions implicating the '921 patent included "significant 'involvement in research [and] commercial activities involving' the claimed subject matter" and explained that standing was present "because DuPont 'has concrete plans' for present and 'future activity that create[] a substantial risk of future infringement or likely cause the patentee to assert a claim of infringement.'" *Id.* (citations omitted).

However, Momenta has now made clear that no concrete plans are afoot.

Momenta also argues that since it was engaged in infringing activity when these proceedings began, it has not lost its standing to complete the review. However, even though Momenta may have been working in pursuit of potentially infringing activity, it is established that jurisdiction must exist throughout the judicial review, and an intervening abandonment of the controversy produces loss of jurisdiction. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) ("[A]n actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." (citations omitted)); *Friends of the Earth*, *Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) ("The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." (internal citation and quotation marks omitted)).

Standing and mootness may not be coextensive in all cases. *See Friends of the Earth,* 528 U.S. at 189–90. However, when the potential for injury has been mooted by events, the federal courts are deprived of jurisdiction. *See California v. San Pablo & Tulare R. Co.*, 149 U.S. 308, 313–14 (1893). If a case does not "present a 'case or controversy' due to developments during litigation, those claims become moot." *Canadian Lumber Trade Alliance v. United States*,

517 F.3d 1319, 1338 (Fed. Cir. 2008). Precedent illustrates exceptions to mootness, for example when the issue has avoided review and is likely to be repeated, or when the defendant voluntarily ceased the challenged activity and the plaintiff seeks to preserve its win. *See, e.g.*, *Milwaukee Police Ass'n v. Bd. of Fire & Police Comm'rs of the City of Milwaukee*, 708 F.3d 921, 929–30 (7th Cir. 2013). In essence, "mootness is the doctrine of standing set in a time frame; that is, the requisite personal interest that must exist at the time of commencement of the litigation (standing) must continue throughout its existence (mootness)." *Id.* at 929 (quotations and alteration omitted).

Here the cessation of potential infringement means that Momenta no longer has the potential for injury, thereby mooting the inquiry.

"The rules of standing, whether as aspects of the Art. III case-or-controversy requirement or as reflections of prudential considerations defining and limiting the role of the courts, are threshold determinants of the propriety of judicial intervention." *Warth*, 422 U.S. at 517–18. It is apparent that Momenta does not have standing to maintain this appeal in the federal courts.

CONCLUSION

Momenta does not have standing to invoke federal appellant jurisdiction, and the appeal is mooted by Momenta's discontinuance of any potentially infringing activity.

APPEAL DISMISSED