United States Court of Appeals for the Federal Circuit

MYLAN LABORATORIES LTD.,
Appellant

v.

JANSSEN PHARMACEUTICA, N.V.,
Appellee

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2021-1071

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2020-00440.

ON MOTION

DEEPRO MUKERJEE, Katten Muchin Rosenman LLP, New York, NY, argued for appellant. Also represented by LANCE SODERSTROM; JOHNJERICA HODGE, ERIC THOMAS WERLINGER, Washington, DC; JITENDRA MALIK, Charlotte,

NC.

PRATIK A. SHAH, Akin Gump Strauss Hauer & Feld LLP, Washington, DC, argued for appellee. Also represented by Z.W. JULIUS CHEN; RUBEN H. MUNOZ, Philadelphia, PA; ANDREW D. COHEN, BARBARA MULLIN, Patterson Belknap Webb & Tyler LLP, New York, NY.

MELISSA N. PATTERSON, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for intervenor. Also represented by WEILI J. SHAW; MICHAEL S. FORMAN, MARY L. KELLY, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED, MOLLY R. SILFEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before NEWMAN, MOORE, and STOLL, *Circuit Judges*.

MOORE, *Circuit Judge*.

O R D E R

Mylan Laboratories Ltd. appeals a Patent Trial and Appeal Board (Board) decision that denied institution of *inter partes* review (IPR) for U.S. Patent No. 9,439,906. *Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, No. IPR2020-00440, 2020 WL 5580472 (P.T.A.B. Sept. 16, 2020) (*Board Decision*). It also seeks mandamus relief.[1] Janssen, the patent owner, moves to dismiss Mylan's

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[1] Mylan cited the All Writs Act, 28 U.S.C. § 1651, in its Notice of Appeal and requested mandamus at argument. *See* Notice of Appeal at 1. We hold that sufficient to seek mandamus relief in the circumstances of this case. *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1312 (Fed. Cir. 2015) (interpreting notice of appeal that cited § 1651 as seeking mandamus).

appeal for lack of jurisdiction. The United States Patent and Trademark Office (Patent Office) intervened and supports Janssen's motion. Because we lack jurisdiction over appeals from decisions denying institution, we grant Janssen's motion to dismiss. Although we have jurisdiction over mandamus petitions challenging such decisions, Mylan has not shown it is entitled to such an extraordinary remedy. Thus, we dismiss Mylan's appeal and deny its request for mandamus.

BACKGROUND

In 2019, Janssen sued Mylan in district court for infringing certain claims in the '906 patent. Less than six months later, Mylan petitioned for IPR of that patent. It raised four grounds for the unpatentability of certain claims, all based on 35 U.S.C. § 103. Opposing institution, Janssen claimed IPR would be an inefficient use of Board resources because of two co-pending district court actions: the suit against Mylan and another suit against Teva Pharmaceuticals USA, Inc. It argued the validity issues in those co-pending actions overlapped with Mylan's petition and that both actions would likely reach final judgment before any IPR final written decision.

The Board agreed with Janssen and denied institution. *Board Decision* at *1–11. In exercising its discretion, the Board applied its six-factor standard for evaluating whether to deny institution in view of an earlier trial date in a co-pending district court proceeding. *See Apple v. Fintiv*, IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020) (precedential) (the *Fintiv* factors[2]). It found

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[2] The factors are: "(1) whether the [district] court granted a stay or evidence exists that one may be granted if a proceeding is instituted; (2) proximity of the [district] court's trial date to the Board's projected statutory deadline for a final written decision; (3) investment in the

substantial overlap between the issues raised in Mylan's IPR petition and the co-pending district court actions. It also found both district court actions would likely reach final judgement before any final written decision. The Board, in part, relied on the Teva trial date, which was only a few weeks away. Thus, the Board concluded it would be an inefficient use of resources to institute IPR.

Mylan appeals. It claims "(1) that the Board's determination to deny institution . . . based on the timing of a separate district-court litigation to which Petitioner is not a party, undermines Petitioner's constitutional and other due process rights; and (2) the Board's continued adoption and application of non-statutory institution standards through *ad hoc* proceedings lie in contrast to congressional intent." Notice of Appeal at 1. It also requests mandamus relief on the same grounds.

DISCUSSION

Janssen's motion implicates two distinct jurisdictional questions: first, whether we have jurisdiction over Mylan's direct appeal, and second, whether we have jurisdiction over Mylan's request for mandamus. We address each question in turn.

I

The jurisdiction of federal courts is limited to those cases and controversies delineated in Article III of the Constitution. And the "[j]urisdiction of the lower federal courts

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parallel proceeding by the [district] court and the parties; (4) overlap between issues raised in the petition and in the parallel proceeding; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) other circumstances that impact the Board's exercise of discretion, including the merits." *Apple v. Fintiv*, IPR2020-00019, 2020 WL 2126495, at *2 (P.T.A.B. Mar. 20, 2020).

is further limited to those subjects encompassed within a statutory grant of jurisdiction." *Ins. Corp. of Ireland v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 701 (1982). Because no statute grants us jurisdiction over appeals from decisions denying institution, we must dismiss Mylan's direct appeal.

Our general grant of jurisdiction, 28 U.S.C. § 1295(a)(4), and the appeal bar, 35 U.S.C. § 314(d), are most relevant here. Read together, those statutes preclude direct appeal from a decision denying institution:

- § 1295(a)(4): [We] shall have exclusive jurisdiction . . . of ***an appeal*** from a decision of [Board] with respect to . . . inter partes review . . . .
- § 314(d): ***No Appeal***. The determination by the Director whether to institute an inter partes review under this section shall be final and ***non-appealable***.

(emphases added). At a first glance, the "appeal from a decision" language in § 1295(a)(4) seems broad, perhaps broad enough to reach an appeal from a decision denying institution. But § 314(d), the more specific statute, dispels any such notion. *See, e.g.*, *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992) ("[I]t is a commonplace of statutory construction that the specific governs the general."). Section 314(d) prevents "appeal" from a decision denying institution. Without the ability to "appeal," parties cannot make use of § 1295(a)(4)'s jurisdictional grant.

Our decision in *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, 749 F.3d 1373 (Fed. Cir. 2014) recognized the limits § 314(d) places on our § 1295 jurisdiction. There, we held "that we may not hear [an] appeal from the Director's denial of [a] petition for *inter partes* review." *Id.* at 1375. We relied "on the structure of the [IPR] provisions, on the language of section 314(d) within that structure, and on our jurisdictional statute read in light of those

provisions." *Id.* Specifically, we determined that § 314(d) barred "an appeal of the non-institution decision" at issue. *Id.* at 1376.[3]

Mylan argues the Supreme Court has undermined *St. Jude*, but that is not so. Every relevant Supreme Court case involved an appeal from a final written decision—not an institution decision. In that posture, 35 U.S.C. § 319 provided jurisdiction: "a party dissatisfied with the final written decision of the [Board] . . . may appeal . . . ." So there was no reason to consider how § 314(d) affects § 1295(a)(4). When the Supreme Court discussed decisions denying institution, however, it suggested such decisions are unreviewable. In *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016), the Court noted that decisions denying institution are "committed to agency discretion." *Id.* (citing 5 U.S.C. §§ 701(a)(2) and 35 U.S.C. § 314(a)). That suggests that, consistent with *St. Jude*, decisions denying institution are not subject to review on direct appeal.

To be sure, the Supreme Court has recognized and relied upon the "strong 'presumption in favor of judicial review.'" *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (quoting *Cuozzo*, 136 S. Ct. at 2140). But that does not undermine *St. Jude* or our reasoning here. Section 314 bars direct appeal from a decision denying institution.

No other statute provides jurisdiction over Mylan's appeal. First, 35 U.S.C. § 319 is limited to "final written decisions under section 318(a)." It does cross reference other

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[3] We see no conflict between our decisions in *St. Jude* and *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1349 (Fed. Cir. 2018). *Arthrex*'s holding that an adverse judgment under 37 C.F.R. § 42.73(b) is appealable pursuant to § 1295 does not conflict with *St. Jude*'s holding that non-institution decisions are nonappealable.

statutes, 35 U.S.C. § 141–44, but nothing in the cross-referenced statutes broadens § 319's plain language. *See id.* § 141(c) (allowing appeal of "final written decision . . . under section 318(a)"). This is not a final written decision. Second, the Administrative Procedure Act, 5 U.S.C. § 701–706, cannot confer jurisdiction over decisions denying institution. *GTNX, Inc.*, 789 F.3d at 1313 (holding the APA "is not a jurisdiction-conferring statute" (internal quotation omitted)). Nor could it overcome § 314(d)'s specific bar on appeals from institution decisions. *Morales*, 504 U.S. at 384 (holding "the specific governs the general").

Therefore, no statute confers jurisdiction over appeals from decisions denying institution. Without such a statute, we lack jurisdiction over those appeals. *See Ins. Corp. of Ireland*, 456 U.S. at 701. Accordingly, we grant Janssen's motion and dismiss Mylan's direct appeal.

II

While there is no avenue for direct appeal of decisions denying institution, we conclude that judicial review is available in extraordinary circumstances by petition for mandamus. Mandamus is not a remedy unique to our Court. The All Writs Act provides that "the Supreme Court and all courts established by an Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions . . . ." 28 U.S.C. § 1651(a). We have long known the All Writs Act "does not expand a court's jurisdiction." *See, e.g.*, *Cox v. West*, 149 F.3d 1360, 1363 (Fed. Cir. 1998). It is, however, "well settled that 'the authority of the appellate court is not confined to the issuance of writs in aid of jurisdiction already acquired by appeal but extends to those cases which are within its appellate jurisdiction although no appeal has been perfected.'" *Telecomms. Rsch. & Action Ctr. v. F.C.C.*, 750 F.2d 70, 76 (D.C. Cir. 1984) (*TRAC*) (quoting *F.T.C. v. Dean Foods Co.*, 384 U.S. 597, 603–04 (1966)). "In other words, section 1651(a)

empowers a federal court to issue writs of mandamus necessary to protect its prospective jurisdiction." *Id.*

We must be careful not to read "prospective" jurisdiction too broadly, however. If every event that "*might* lead to a filing before an agency or lower court, which *might* lead to an appeal to this court" fell within that category, our prospective jurisdiction would be boundless. *In re Tennant*, 359 F.3d 523, 529 (D.C. Cir. 2004); *accord In re Donohoe*, 311 F. App'x 357, 358 (Fed. Cir. 2008) (non-precedential) (citing *Tennant*). "[I]t is easy enough to spin out 'for want of a nail' scenarios from any set of facts that could eventually lead to this court." *Tennant*, 359 F.3d at 529. But when a party has "at least [taken] the first preliminary step that might lead to appellate jurisdiction in this court in the future," prospective jurisdiction has been triggered. *Id.* The preliminary step of an IPR is the filing of a petition, and the Director has the discretion to grant or deny such petition. 35 U.S.C. § 314(a); *Cuozzo*, 136 S. Ct. at 2140. From beginning to end, the "petition . . . guide[s] the life of [IPR] litigation." *SAS*, 138 S. Ct. at 1356.

And we have exclusive jurisdiction over any permissible appeal from a final decision of the Board in an IPR. In general, 28 U.S.C. § 1295(a)(4) provides us "exclusive jurisdiction" over Board decisions to the extent they are appealable. Likewise, 35 U.S.C. § 141(c) allows "a party to an *inter partes* review . . . who is dissatisfied with the final written decision" to "appeal the Board's decision *only* to" this Court. "The structure of th[is] statutory scheme . . . reveals congressional intent to preclude district court review of IPR decisions." *Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1362 (Fed. Cir. 2020). And we are aware of no other potential forum for review of IPR decisions. *See generally* 28 U.S.C. § 1338(a) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents . . . ."). Thus, this Court alone has prospective jurisdiction once a petitioner seeks IPR.

When institution is denied, the appeal bar in § 314(d) prevents any direct appeal. But that statute is silent with respect to mandamus. There is no reason, therefore, to think § 314(d) also divests us of mandamus jurisdiction. In fact, when the Board denies institution, our mandamus jurisdiction is especially important. Like unreasonable delay of agency action, a decision denying institution "defeats [our] prospective jurisdiction." *Cf. Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 43 (D.C. Cir. 2004) (holding mandamus review is available when an agency withdraws a proposed rule and the court had exclusive jurisdiction to review any promulgated rule). A decision denying institution prevents the Board from issuing any final decision that falls within our direct appellate jurisdiction. We must, therefore, be able to protect our prospective jurisdiction through mandamus.[4] We conclude that challenges to the denial of institution fall within the *TRAC* rubric. To protect our future jurisdiction, we have jurisdiction to review any petition for a writ of mandamus denying institution of an IPR.

Though not explicitly, precedent confirms the existence of our mandamus jurisdiction. Several petitioners have sought mandamus relief from some aspect of an institution

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[4] We note that the government agrees that this court has jurisdiction to review a petition for writ of mandamus challenging the denial of institution in order to protect its jurisdiction. Oral Arg. at 29:12–29:44 (government: "I don't think there is some sort of jurisdictional limit" for seeking mandamus), 31:25–32:20 (government: The Federal Circuit can "act in aid of its jurisdiction . . . by entertaining petitions for writs of mandamus," applying *TRAC*), http://oralarguments.cafc.uscourts.gov/default.aspx?fl=21-1071_02122021.mp3; *cf. id.* at 01:05:36–06:14 (Janssen: "I agree with everything [the government] said about mandamus.").

decision. *See, e.g.*, *In re Power Integrations, Inc.*, 899 F.3d 1316, 1318 (Fed. Cir. 2018); *GTNX, Inc.*, 789 F.3d at 1313; *In re Dominion Dealer*, 749 F.3d 1379, 1381 (Fed. Cir. 2014); *see also, e.g.*, *Apple Inc. v. Optis Cellular Tech., LLC*, No. 2021-1043, 2020 WL 7753630, at *1 (Fed. Cir. Dec. 21, 2020) (non-precedential); *In re Cisco Sys. Inc.*, 834 F. App'x 571, 573 (Fed. Cir. 2020) (non-precedential). Each time, we held the petitioner had failed to show a clear right to relief and denied mandamus rather than dismissed the petition. Though the opinions are silent as to jurisdiction, to reach that question, we must have had jurisdiction. In other cases, we have explicitly suggested the possibility of mandamus relief: "mandamus may be available to challenge the PTO's decision to grant a petition to institute IPR after the Board's final decision in situations where the PTO has clearly and indisputably exceeded its authority." *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1274 (Fed. Cir. 2015), *aff'd on other grounds sub nom., Cuozzo*, 136 S. Ct. 2131.

Ultimately, Mylan triggered our exclusive jurisdiction by petitioning for IPR. It set the administrative machinery into motion and opened an avenue for appellate jurisdiction, no matter how "prospective or potential that jurisdiction might be." *Tennant*, 359 F.3d at 529. And we may consider any petition for a writ of mandamus in order to protect that jurisdiction. Accordingly, we have jurisdiction to consider Mylan's request for mandamus on the merits.

III

Mylan believes it is entitled to mandamus relief based on two statutory challenges and one constitutional challenge. First, it faults the Patent Office for adopting the *Fintiv* standard through a precedential Board decision, rather than notice-and-comment rulemaking. By doing so, Mylan claims, the Board exceeded the scope of its statutory authority. *See* 35 U.S.C. § 316(a)(2). Second, Mylan argues the *Fintiv* standard unlawfully shortens the limitations

period for filing an IPR. *Id.* § 315(b). Finally, Mylan contends the *Fintiv* standard is unconstitutional as applied here. It claims that its due process rights were violated when the Board relied on the Teva litigation to deny institution.

Mandamus is a "drastic and extraordinary remedy reserved for really extraordinary causes." *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380 (2004). "[O]nly exceptional circumstances amounting to a judicial usurpation of power, or a clear abuse of discretion will justify" such relief. *Id.* (internal citations and quotation omitted). "As the writ is one of the most potent weapons in the judicial arsenal, three conditions must be satisfied before it may issue." *Id.* (internal quotation and citation omitted). The petitioner must: (1) show that it has a clear and indisputable legal right; (2) show it does not have any other adequate method of obtaining relief; and (3) convince the court that the writ is appropriate under the circumstances. *Id.* at 380–81 (citation omitted).

When a mandamus petition challenges a decision denying institution, the mandamus standard will be especially difficult to satisfy. The scope of our review of a mandamus petition over a denial of institution is very narrow. As the Supreme Court has explained, "the [Patent Office]'s decision to deny a petition is a matter committed to the Patent Office's discretion. *See* [5 U.S.C.] § 701(a)(2); 35 U.S.C. § 314(a) (no mandate to institute review)." *Cuozzo*, 136 S. Ct. at 2140. The Director is permitted, but never compelled, to institute an IPR. And no petitioner has a right to such institution. For example, the Director is free, as in this case, to determine that for reasons of administrative efficiency an IPR will not be instituted, as agencies generally are free, for similar reasons, to choose not to initiate enforcement proceedings. *Heckler v. Chaney*, 470 U.S. 821, 830–32 (1985). And the Supreme Court has determined that such a decision is committed to agency discretion by

law. *Cuozzo*, 136 S. Ct. at 2140. Given this determination and the statute's bestowal of discretion on the Director combined with its prohibition on appeal of such decisions, we conclude that there is no reviewability of the Director's exercise of his discretion to deny institution except for colorable constitutional claims. *Cf., e.g.*, *Webster v. Doe*, 486 U.S. 592, 603–04 (1988) (holding that a "colorable" constitutional claim was reviewable in district court even where the substance of the underlying termination decision was not); *Woodward v. United States*, 871 F.2d 1068, 1072 (Fed. Cir. 1989) ("While the statute and cited authorities indicate that the Secretary's discretion is generally unfettered, employment actions claimed to be based on constitutionally infirm grounds are nevertheless subject to judicial review.").[5]

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[5] We need not decide whether any petition for writ of mandamus challenging the Patent Office's *grant* of institution could ever be meritorious. Decisions granting institution involve a fundamentally different calculus. *See Cuozzo*, 136 S. Ct. at 2153 n.6 (Alito, J., concurring-in-part and dissenting-in-part) ("A patent challenger does not have nearly as much to lose from an erroneous denial of inter partes review as a patent owner stands to lose from an erroneous grant of inter partes review."). The majority in *Cuozzo* cited the dissent's footnote 6 with approval. *Id.* at 2140.

We note that the Supreme Court has suggested decisions granting institution may be reviewable (to a limited extent) on direct appeal from a final written decision. *See Cuozzo*, 136 S. Ct. at 2141–42; *see also SAS*, 138 S. Ct. at 1359 (reviewing "exactly the sort of question" *Cuozzo* left open). The availability of review on direct appeal may preclude mandamus, which requires that no other adequate avenue for relief be possible. *See Cheney*, 542 U.S. at 380.

While we need not explore the outer contours of possibility, it is difficult to imagine a mandamus petition that challenges a denial of institution and identifies a clear and indisputable right to relief. Certainly, this is not such a petition. Mylan lacks a clear and indisputable right to review of the Patent Office's determination to apply the *Fintiv* factors or the Patent Office's choice to apply them in this case through adjudication rather than notice-and-comment rulemaking. Given the limits on our reviewability, Mylan's *ultra vires* argument cannot be a basis for granting the petition for mandamus. Mylan's time bar argument under § 315(b) fails for the same reason.

Finally, Mylan fails to state a colorable claim for constitutional relief. It does not identify a deprivation of "life, liberty, [or] property," so any procedural due process challenge is foreclosed. *Stone v. F.D.I.C.*, 179 F.3d 1368, 1375 (Fed. Cir. 1999) ("Procedural due process requires that certain substantive rights—life, liberty, and property—cannot be deprived except pursuant to constitutionally adequate procedures."); *see also* Oral Arg. at 44:38–46:15 (questioning whether deprivation of a property right is required for a due process claim, but not identifying any property right). To be sure, we have held that a judgment must not bind a person "who was not party or privy and therefore has never had an opportunity to be heard." *See, e.g.*, *In re Trans Tex. Holdings Corp.*, 498 F.3d 1290, 1297 (Fed. Cir. 2007). But that rule is inapposite here. Mylan will not be bound by the Teva litigation; it is free to litigate the '906 patent claims' validity in its own district court case.

Likewise, we are aware of no "history [or] tradition" that supports a fundamental right to have the Board consider whether to institute one's IPR petition based only upon co-pending litigation to which you are a party. *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997). That is, Mylan had no right for its petition to be considered without reference to the Teva litigation and no right to an IPR.

Thus, Mylan has also failed to state a colorable claim under substantive due process.

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For the foregoing reasons, we lack jurisdiction over Mylan's direct appeal. Though we have jurisdiction over its request for mandamus, Mylan has failed to show a clear right to relief. Accordingly,

IT IS ORDERED THAT:

(1) Janssen's motion is granted;

(2) Mylan's petition for a writ of mandamus is denied; and

(3) Costs are awarded to Janssen.

FOR THE COURT

March 12, 2021
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court