No. 18-916

IN THE
Supreme Court of the United States

THRYV, INC., FKA DEX MEDIA, INC.,

Petitioner,

v.

CLICK-TO-CALL TECHNOLOGIES, LP, ET AL.

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Those efforts produce the cutting-edge medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day.

Over the past decade, PhRMA's members have secured FDA approval of more than 300 new medicines. Such results are not obtained cheaply. PhRMA members have invested more than $900 billion in research and development since 2000. In 2018 alone, PhRMA members invested an estimated $79.6 billion in development of new medicines.

PhRMA member companies rely on the patent system to protect the innovations resulting from those enormous investments. Moreover, PhRMA's members are sometimes defendants in patent

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part, that no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person other than *amicus*, its members, or its counsel made such a monetary contribution. Counsel for all parties consented to the filing of this brief.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Nov. 4, 2019).

infringement actions and in inter partes review proceedings. And PhRMA's members buy, sell, and license patents. PhRMA thus has unique and uniquely balanced insights on the implications of the issues before the Court, as well as the need for an efficient patent system that fosters, rewards, and protects innovation and competition alike.

Accordingly, PhRMA seeks to advance public policies that foster innovation and encourage its members' investments. To those ends, PhRMA seeks to remove barriers that may arise in the nation's patent and other systems for protecting the intellectual property of its members—including as *amicus curiae* in significant patent matters before this Court. *See, e.g., Oil States Energy Services, LLC, v. Greene's Energy Group, LLC,* No. 16-712; *Cuozzo Speed Tech., LLC v. Lee*, No. 15-446.

This case presents a question of critical importance for members of PhRMA and all other patent holders: whether federal court review is authorized of the Patent Trial and Appeal Board's ruling that a petition is not time-barred under 35 U.S.C. § 315(b). That provision deprives the Board of authority to conduct inter partes review if the party seeking such review was served with a complaint alleging infringement of the patent at issue more than one year prior. The Federal Circuit correctly held that judicial review is available of a challenge to the Board's exercise of authority based on its determination that a petition is not time-barred under Section 315(b). A decision to the contrary would threaten the rights of patent holders and could deter innovation.

INTRODUCTION AND SUMMARY OF ARGUMENT

After the U.S. Patent and Trademark Office ("Patent Office") has granted a patent, Article III "courts have traditionally adjudicated" subsequent challenges to the patent's validity. *Oil States Energy Serv., LLC v. Greene's Energy Grp., LLC,* 138 S. Ct. 1365, 1378 (2018). Congress has maintained this central role for the judiciary in the adjudication of patent disputes to this day. Notably, federal district courts retain original jurisdiction over any civil actions alleging infringement of a patent. *See* 28 U.S.C. § 1338.

In enacting the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), Congress created mechanisms by which the Patent Office may in certain circumstances reconsider its prior grant of a patent. One such procedure is inter partes review.

Congress limited its grant of authority to the agency to conduct inter partes review in certain specified circumstances. In particular, Congress provided in Section 315(b) that "[a]n inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent." 35 U.S.C. § 315(b).

Petitioner in this case does not deny that the agency lacks authority to institute inter partes review when a petition is time-barred under Section 315(b). Instead, Petitioner makes the remarkable contention

that Article III courts have no authority to review the agency's exercise of its authority based on the agency's determination that a petition is not time-barred by Section 315(b).

Petitioner seeks support for this argument in Section 314(d), a provision which renders certain determinations nonappealable: "The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." 35 U.S.C. § 314(d). According to Petitioner, Section 314(d) insulates from judicial review any "integral part of the institution decision," Petitioner's Br. at 13, even if it is the determination of whether a statutory prerequisite to the agency's exercise of authority is met.

Petitioner is mistaken.

First, the plain text of Section 314(d) makes clear that its no-appeal provision does not extend to the agency's exercise of authority over a petition that is time-barred by Section 315(b). Section 314(d) applies only to a determination to institute "under this section"—that is, under Section 314, not under Section 315. Further, the statutory text and structure confirm that Section 314(d) renders nonappealable only the agency's discretionary determination under Section 314(a)—namely, whether to institute inter partes review based on a conclusion that a petitioner has a reasonable likelihood of prevailing with respect to at least one of the claims challenged. It does not insulate from judicial review the agency's determination of the mandatory prohibition in Section 315(b) on conducting inter partes review of a petition that is not filed

within a year of service of an infringement complaint, a rule which governs the relation of inter partes review to proceedings in federal court.

Second, general principles of administrative law and this Court's precedent confirm that statutory reading. The Section 314(a) determination of whether to institute review based on a reasonable likelihood of a petition succeeding on at least one of the claims challenged is the type of determination commonly committed to agency discretion. By contrast, the Section 315(b) time bar goes to the limits of the agency's statutory authority and Congress's desire for inter partes review not to interfere unduly with court proceedings. Questions of that type are rarely, if ever, insulated from judicial review.

This statutory reading is also consistent with this Court's precedent. As this Court held in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018): "Given the strength of th[e] presumption [in favor of judicial review] and the statute's text . . . § 314(d) precludes judicial review only of the Director's initial determination under § 314(a) that there is a reasonable likelihood that the claims are unpatentable on the grounds asserted and review is therefore justified." 138 S. Ct. at 1359 (internal quotation marks and citation omitted). Petitioner identifies no basis for overcoming the presumption in favor of judicial review of whether the agency has exercised its authority in excess of the time-bar of Section 315(b).

Third, Petitioner's contrary reading would effectively vest the agency with *carte blanche* to define the

limits of its authority. Allowing the agency this unprecedented degree of independence would increase the risk of unauthorized inter partes review, thereby denying patent holders repose and stripping them of the certainty, stability, and predictability they need to justify the tremendous investments necessary to develop and bring to market patentable products.

ARGUMENT

I. THE STATUTE'S TEXT AND STRUCTURE PERMIT JUDICIAL REVIEW OF THE AGENCY'S DETERMINATION THAT INTER PARTES REVIEW IS NOT TIME-BARRED UNDER SECTION 315(b).

A. Section 314(d) expressly states that "[t]he determination by the [agency] whether to institute an inter partes review *under this section* shall be final and nonappealable" 35 U.S.C. § 314(d) (emphasis added). As an initial matter, the determinations made nonappealable by this provision are thus clearly limited to determinations made under Section 314.

Section 314(d)'s use of permissive language (i.e., "*whether* to institute review") to identify the determinations that are not appealable further clarifies that Section 314(d) refers specifically to the agency's determinations under Section 314(a). Section 314(a) identifies the threshold circumstance where the agency may exercise discretion to institute a review—i.e., when the agency has determined that a petition and any response show a challenge to at least one claim is reasonably likely to prevail. And Section

314(a) provides that the agency may not institute inter partes review "unless" that threshold likelihood of the petition prevailing against a claim is met. But Section 314(a) does not require that such a determination be made, nor that the agency institute inter partes review where the threshold is met. The agency thus has discretion to make the threshold determinations of whether a petition is reasonably likely to prevail against a claim and, if it is, whether to institute review. It is this exercise of discretion that the no-appeal provision of Section 314(d) renders nonappealable, not every feature of the institution decision, as Petitioner contends. *See SAS Institute*, 138 S. Ct. at 1359.

By contrast, Section 315(b) sets forth a mandatory prohibition against any inter partes review "if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent." 35 U.S.C. § 315(b).

To begin with, the no-appeal provision of Section 314(d) does not apply to the time bar under Section 315(b), because that time bar is not part of, nor closely related to, the discretionary determination made *under* Section 314 that is rendered nonappealable by Section 314(d). That the Section 315(b) prohibition affords no discretion to the agency as to whether to institute, but unequivocally prohibits exercise of agency authority over a petition time-barred by Section 315(b), further emphasizes that it does not fall within the Section 314(d) no-appeal provision.

If Congress had meant to sweep *every* determination relating to instituting inter partes review into the scope of the Section 314(d) no-appeal provision, as Petitioner suggests, it could have instead referred to the agency's determination whether to institute an inter partes review "under this chapter," as it did elsewhere in the AIA. *Id.* § 314(b) ("The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months . . . ."); *see, e.g., id.* § 315(e)(1)-(2); *id.* § 316(a)(1), (4), (11); *id.* § 317(1).

B. The structure of the statutory framework crafted by Congress reinforces the limited reach of the Section 314(d) no-appeal provision.

Section 314 is directed toward internal agency action and decisionmaking relating to the threshold consideration of a petition's likely merits, worthiness for agency review of the patent previously issued, as well as the timing for the agency's action and notification of the parties and the public. The focal point of Section 314 is subsection (a), which as discussed grants the agency discretion to assess whether a petition has a reasonable likelihood of prevailing with respect to at least one of the claims challenged, and, if it does, whether institution of inter partes review is warranted. As this Court noted in *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), the "kind of initial determination at issue [under Section 314(a)] is akin to decisions which, in other contexts, [this Court has] held to be unreviewable." *Id.* at 2140.

By contrast, Section 315 addresses the relationship between inter partes review and other

proceedings, including proceedings in federal court. That is far from a type of agency action that would ordinarily be insulated from judicial review. Rather, the fact that Section 315 addresses the interaction between agency action and court proceedings highlights the importance of judicial review.

For instance, the Section 315(b) time-bar applies when a petitioner for inter partes review already has been served with a complaint for infringement. In such circumstances, that alleged infringer must petition for inter partes review no more than a year after service of the complaint against it. *See* 35 U.S.C. § 315(b). In addition to providing repose to the patent holder, that time bar is significant because once that year has passed, a court may exercise jurisdiction over an infringement action involving the asserted patent knowing that no inter partes review can be sought by the infringement defendant.

Indeed, courts often stay their preexisting infringement matters if an inter partes review is filed, to preserve resources and foster consistent resolutions. *See Murata Mach. USA v. Daifuku Co., Ltd.*, 830 F.3d 1357, 1361 (Fed. Cir. 2016) ("District courts typically analyze stays [pending the resolution of inter partes review] under a three-factor test: (i) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (ii) whether a stay will simplify the issues in question and trial of the case; and (iii) whether discovery is complete and whether a trial date has been set."); *Granting accused infringer's motion to stay infringement suit pending reexamination*, 4 Annotated Patent Digest § 25:134 (last accessed Oct. 28, 2019) (cataloguing cases in

which stays have been granted pending the resolution of inter partes review). But if the agency is unchecked in exercising its authority over petitions that are filed past that one-year bar, adjudication of pending infringement actions will be undermined.

Section 315 also contains a prohibition under subsection (a) against the agency exercising authority over an inter partes review petition when a civil action already has been initiated by the petitioner itself challenging the patent's validity. Like the Section 315(b) time bar, the Section 315(a) bar against agency review has a direct effect on court proceedings. If Section 315(a) were not subject to judicial review (a likely corollary of Petitioner's statutory reading), the agency's exercise of authority over such a later-filed inter partes review petition would directly conflict with the court proceeding, contrary to the clear statement of Congress.[3] Petitioner identifies no reason to suspect Congress intended to allow for such a result.

II. THE JUDICIAL REVIEW DISTINCTION CONGRESS ESTABLISHED BETWEEN SECTIONS 314 AND 315 IS CONSISTENT

[3] Indeed, Congress further provided that when a petitioner files a civil action challenging the validity of the patent after it already has filed an inter partes review petition to challenge it, that civil action is automatically stayed unless the patent owner moves to lift the stay or files a counterclaim of civil action for infringement, or the petitioner moves to dismiss the civil action. *See* 35 U.S.C. § 315(a)(2).

WITH ADMINISTRATIVE LAW PRINCIPLES AND THIS COURT'S PRECEDENT

A. That the no-appeal provision in Section 314(d) applies only to the agency's threshold determinations under Section 314(a), and not to the statutory limits on agency authority in Section 315(b), accords with general principles of administrative law and the presumption of reviewability of agency action.

Notwithstanding that the Section 314(a) threshold determination is not reviewable, the ultimate determination of a patent's validity is subject to judicial review. If the agency institutes inter partes review upon concluding that the threshold has been met, the agency is required to issue a final written decision as to the patentability of any patent claim challenged. *See* 35 U.S.C. § 318(a). That final written decision is made expressly subject to judicial review under the AIA. *See id.* § 319. The no-appeal provision of Section 314(d) in that context functions to constrain the parties on appeal from reaching back to argue over whether the institution of inter partes review was justified based on the original petition, and to litigate instead the merits of the agency's final written decision. Conversely, if the agency declines to institute inter partes review because of the time-bar under Section 315(b), in most instances the patent holder already has an infringement action pending against the petitioner in which the petitioner can contest the patent's validity (indeed, in many cases, it will have been the filing of a complaint in that very litigation that triggered the time bar). *See* J. Steven Baughman et al., *Coordinating PTAB and District Court Litigation*, Prac. L.J., Dec. 2014/Jan. 2015, at 1 ("[A]s the

two-year anniversary of post-grant patentability challenges before the PTAB passed, 80% of PTAB proceedings involved a related, concurrent district court patent case.").

If Petitioner were correct, however, that the no-appeal provision of Section 314(d) extends to the Section 315(b) time bar, the determination of the agency's statutory authority over a petition that is challenged as time-barred may *never* be susceptible to judicial review, even after the agency's final written decision is on review in federal court. And that unreviewability would create an exercise of judicial review by the Federal Circuit over the agency's final written decision on petitions that the agency erred in finding not time-barred by Section 315(b), thereby invalidly expanding litigation of time-barred petitions when Congress intended to exclude them even from initial agency review.

Allowing judicial review of final agency action and agency determination that statutory requirements are met for the exercise of agency authority, but not of agency discretionary determinations to institute agency action that are later subsumed by the final action, is consistent with general principles of administrative law reflected in the Administrative Procedure Act ("APA") and this Court's precedent. *Compare* 5 U.S.C. § 704 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.") *with Heckler v. Chaney*, 470 U.S.

821, 832 (1985) ("[A]n agency's decision not to take enforcement action . . . has traditionally been committed to agency discretion, and we believe that the Congress enacting the APA did not intend to alter that tradition.") (internal quotation marks and citation omitted).

Furthermore, judicial review of ultra vires agency action is generally presumed available even absent explicit statutory provisions authorizing such review. *See Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327 (D.C. Cir. 1996) ("If a plaintiff is unable to bring his case predicated on either a specific or a general statutory review provision, he may still be able to institute a non-statutory review action."). For instance, in *Leedom v. Kyne*, 358 U.S. 184, 187 (1958), this Court was asked whether a preliminary decision of the National Labor Relation Board relating to the ultra vires certification of an exclusive collective bargaining agent was reviewable, notwithstanding that the judicial review provisions of the National Labor Relations Act explicitly permitted judicial review only of "final orders." Because the suit at hand was "not one to 'review,' in the sense of that term as used in the Act, a decision of the Board made within its jurisdiction," but "[r]ather it is one to strike down an order of the Board made in excess of its delegated powers and contrary to a specific prohibition in the Act," the certification decision was found reviewable. *Id.* at 188 (quoting Section 9(b)(1) of the National Labor Relations Act, as amended 29 U.S.C. § 159(b)(1)).

That logic carries over to the present circumstances, where the agency's exercise of authority over a petition asserted to be time-barred concerns the

agency's statutory authority to have instituted inter partes review in the first place.

B. The distinction created by Congress between the nonappealability of Section 314(a) discretionary determinations and the reviewability of statutory limitations on the agency's authority is also consistent with this Court's precedent.

In *SAS*, the Court held that judicial review is appropriate of the agency's determinations on its own statutory authority to conduct inter partes review. *See* 138 S. Ct. at 1359. The Court there addressed the question whether the agency's practice of "partial institution," whereby the agency had begun instituting inter partes review on only some, rather than all, of the claims challenged in a petition, violated 35 U.S.C. § 318.[4] The agency defended this practice by, *inter alia*, claiming that the Court had no jurisdiction to review it. The Court explained that the agency "reads [Section 314(d) and *Cuozzo*, 136 S. Ct. at 2139-2142] as foreclosing judicial review of any legal question bearing on the institution of inter partes review—including whether the statute permits [its] 'partial institution' practice." *SAS*, 138 S. Ct. at 1359.

This Court rejected that argument, clarifying the limited scope of the no-appeal provision in Section 314(d) and its own ruling in *Cuozzo*. The Court explained that, "[g]iven the strength of th[e]

[4] Section 318(a) provides that "[i]f an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d)."

presumption [in favor of judicial review] and the statute's text, *Cuozzo* concluded that § 314(d) precludes judicial review *only of the Director's initial determination under § 314(a)* that there is a reasonable likelihood that the claims are unpatentable on the grounds asserted and review is therefore justified." 138 S. Ct. at 1359 (internal quotation marks and citation omitted, emphasis added). And the *SAS* Court noted that *Cuozzo* had emphasized that "§ 314(d) does not 'enable the agency to act outside its statutory limits.'" *Id.* The *SAS* Court therefore concluded that Section 314(d) did not preclude judicial review of the agency's "partial institution" practice, ultimately striking down the practice as violating Section 318.

As in *SAS*, a challenge to the agency's determination that a petition is not time-barred under Section 315(b) "does not seek to challenge the [agency's] conclusion that it showed a reasonable likelihood of success sufficient to warrant institut[ing] an inter partes review." *Id.* at 1359 (internal quotation marks and citation omitted). Rather, because the ruling by the agency that a petition is not time-barred under Section 315(b) concerns whether the agency "exceeded its statutory bounds, judicial review remains available." *Id.* (internal quotation marks and citation omitted).

Even if there were any ambiguity on this point, this Court's precedent makes clear that it would be resolved in Respondent's favor in light of the "strong presumption" favoring judicial review of executive action. *Id.* (internal quotation marks and citation omitted). This presumption may only be "overcome by clear and convincing indications, drawn from specific

language, specific legislative history, and inferences of intent drawn from the statutory scheme as a whole that Congress intended to bar review." *Cuozzo*, 136 S. Ct. at 2140 (internal quotation marks and citation omitted). As discussed *supra*, Petitioner has identified no such indications (much less clear and convincing ones), that Congress in enacting the AIA intended to foreclose judicial review of the agency's determination that a petition is not time-barred under Section 315(b).

III. PETITIONER'S CONTRARY READING OF THE STATUTE WOULD UNDERMINE THE PREDICTABILITY NECESSARY FOR STAKEHOLDERS IN THE PATENT SYSTEM.

Judicial review of whether the agency's exercise of authority to conduct inter partes review violates the Section 315(b) time bar would provide repose to patent holders and greater certainty to all relevant stakeholders. It would ensure that Section 315(b) is given its intended effect and that the agency's determination that it has authority over a petition challenged as time barred under the statute is not left unreviewed.

This predictability is particularly essential given the substantial investments of time and money that patent owners must make to bring to market patentable products. *See, e.g.,* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 31 (2016) (finding that developing and bringing to market a new drug costs on average $2.6 billion). Indeed, PhRMA's

members invest billions of dollars each year in researching and developing new therapies. Being forced to undergo inter partes review when Congress has expressly prohibited it unnecessarily and unfairly subjects patent holders to even greater expense and delay.

Undergoing an unauthorized inter partes review also creates added legal risk. This risk arises in part because the PTAB has been more favorable to challengers than the federal courts have been. Notably, while four out of five instituted inter partes reviews lead to at least one claim being found unpatentable, patents are invalidated less than half of the time in federal court.[5] Moreover, when inter partes review is sought by an infringement defendant only once district court litigation is well under way, removal of judicial review of the time bar that imposes a one-year deadline after being served with a complaint could "allow[] infringement defendants to test the waters of district court litigation—from answer, to both fact and expert discovery, to motions to dismiss and potentially for summary judgment—before halting the infringement suit against them" by seeking a stay of the infringement suit pending resolution of inter partes review. Jacob S. Sherkow, *Administering Patent Litigation*, 90 Wash. L. Rev. 205, 236 (2015).

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[5] *Compare* U.S. Patent and Trademark Office, *Trial Statistics IPR, PGR, CBM: Patent Trial and Appeal Board* (Sept. 2019), https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-09-30.pdf *with* John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014).

Allowing judicial review of the agency's determination that its exercise of authority is not precluded by the statutory time bar would reduce the chance for ultra vires institutions of inter partes review. That would provide repose to patent holders and far greater certainty to all stakeholders. Under 35 U.S.C. §§ 141(c), 319, appeal from a final written decision reached in an inter partes review is permitted to the United States Court of Appeals for the Federal Circuit. Particularly as the Federal Circuit is the *only* court of appeals with jurisdiction to hear such an appeal, allowing it—along with this Court on any further review—to safeguard the statutory limitations on inter partes review will provide clarity to patent holders and patent challengers alike.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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