

No. 19-1381

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IN THE  
Supreme Court of the United States

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BIODELIVERY SCIENCES INTERNATIONAL, INC.,  
*Petitioner,*

v.

AQUESTIVE THERAPEUTICS, INC.,  
*Respondent.*

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**On Petition For A Writ of Certiorari To The United  
States Court of Appeals for the Federal Circuit**

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**BRIEF IN OPPOSITION**

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JAMES F. HIBEY  
ALICE E. LOUGHRAN  
*Counsel of Record*  
STEPTOE & JOHNSON LLP  
1330 Connecticut Ave., N.W.  
Washington, D.C. 20036  
(202) 429-6202  
aloughran@steptoe.com

JOHN L. ABRAMIC  
STEPTOE & JOHNSON LLP  
227 W. Monroe St.  
Suite 4700  
Chicago, IL 60606

JAMIE LUCIA  
STEPTOE & JOHNSON LLP  
One Market Plaza  
Spear Tower, Suite 3900  
San Francisco, CA 94105

*Counsel for Respondent*

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**CORPORATE DISCLOSURE STATEMENT**

Pursuant to Supreme Court Rule 29.6, the undersigned counsel states that Aquestive Therapeutics, Inc. is a nongovernmental corporate entity that has no parent corporation and that there is no publicly held company or affiliate that owns 10% or more of the stock of Aquestive Therapeutics, Inc.

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**BRIEF IN OPPOSITION**

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**INTRODUCTION**

This case is, in short, about Petitioner’s complaint over the meaning of a Federal Circuit panel’s remand order and Petitioner’s disagreement with that same panel’s interpretation and enforcement of its own order. That Federal Circuit panel remanded inter partes reviews (“IPR”) to the Patent Trial and Appeal Board (“the Board”) with instructions to implement this Court’s decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348(2018). On remand, the Board issued decisions not to institute the IPRs; and thereafter, on the second-round appeal, the same Federal Circuit panel applied

the plain language of 35 U.S.C. § 314(d) to hold that judicial review of a decision whether to institute is not available. This non-controversial holding, which is not subject to any conflicting interpretations, led the Federal Circuit to dismiss Petitioner's appeal as dictated by precedent. In dismissing Petitioner's appeal, the Federal Circuit panel also explicitly confirmed that the Board complied with its original remand order. Pet. App. 8a-9a. Accordingly, there are no issues that would justify discretionary review by this Court.

Petitioner argues here that the Federal Circuit and the Board did not apply *SAS* correctly. However, the Federal Circuit panel reviewed the Board's non-institution decisions, issued following remand from the same panel, to ensure that the Board did properly follow the panel's remand order and this Court's *SAS* decision. *See* Pet. App. 8a. The Federal Circuit determined that the Board, by considering Petitioner's original IPR petitions and by exercising its discretionary authority not to institute, complied with both its original remand order to the Board and this Court's *SAS* directive to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. Because the Federal Circuit properly applied the plain language of the relevant statutes and ensured that the Board complied with its original remand order and with this Court's *SAS* decision, there are no conflicting decisions or other important questions that would warrant further review by this Court.

Petitioner attempts to fashion additional disputes where none exist, raising arguments about "due

process” and alleged “negation” and “nullification” of judicial review. However, all of these criticisms are fact-specific and relate only to the procedural posture of this single matter. Contrary to Petitioner’s protests, these fact-specific criticisms of the Federal Circuit’s review of the Board’s non-institution decisions do not establish any legitimate risk that future cases could be impacted by the result here. In fact, in light of this Court’s *SAS* decision, all institution decisions issued by the Board are now binary (*i.e.*, “either institute review or don’t”); so, going forward, any issues that arose in the proceedings here are therefore obsolete going forward. As such, there are no “compelling reasons” for this Court to exercise its discretion to undertake further review of the straightforward result of this case. *See* SUP. CT. R. 10.

## **COUNTER-STATEMENT OF THE CASE**

### **A. Statutory Background**

This case concerns inter partes review. “Inter partes review is an administrative process in which a patent challenger may ask the U.S. Patent and Trademark Office (PTO) to reconsider the validity of earlier granted patent claims.” *Thryv, Inc. v. Click-to-Call Technologies, LP*, 140 S. Ct. 1367, 1368 (2020). When a petition for inter partes review is filed, the PTO Director must decide whether to institute review. 35 U.S.C. § 314(a). The Director has delegated institution authority to the Patent Trial and Appeal Board (Board). 37 C.F.R. § 42.4(a) (2019).

The governing statute does not require the agency to grant inter partes review in any circumstance. It

does, however, identify certain circumstances in which the agency may not institute such review. The Board may not institute review unless the agency determines “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

The agency’s determination “whether to institute an inter partes review” is “final and nonappealable.” 35 U.S.C. § 314(d). *See also Thryv*, 140 S. Ct. at 1373-77; *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139 (2016) (Board decisions not to institute inter partes review are “not appealable” because “that is what § 314(d) says”).

If the Board elects to institute IPR, the Board conducts a proceeding to evaluate the challenged claims’ validity. 35 U.S.C. § 316; 37 C.F.R. Pt. 42, Subpt. A. At the conclusion of the proceeding—if review “is instituted and not dismissed”—the Board “issue[s] a final written decision with respect to the patentability of the challenged claims.” 35 U.S.C. § 316. “A party dissatisfied with the final written decision . . . may appeal the decision” to the Court of Appeals for the Federal Circuit. 35 U.S.C. § 319.

## **B. Factual Background**

Aquestive is the assignee of U.S. Patent No. 8,765,167 (“the ’167 patent”). More than five years ago, on October 28, 2014, Petitioner filed three IPR petitions attempting to invalidate the ’167 patent on 17 different asserted grounds. Pet. App. 2a. Upon initial consideration of the IPR petitions, the Board concluded that Petitioner failed to meet the threshold level for review for the vast majority of the

asserted grounds. Pet. App. 2a. As a result, the Board instituted review on the remaining three grounds and ultimately sustained the patentability of the challenged claims on those three grounds. Pet. App. 2a.

While Petitioner’s appeal of the Board’s patentability decision to the Federal Circuit was pending, this Court issued the *SAS* decision. Pet. App. 2a. The *SAS* Court clarified that 35 U.S.C. § 314 “indicates a binary choice—either institute review or don’t.” *SAS Institute*, 138 S. Ct. at 1355. The Federal Circuit panel then granted a motion to remand the IPRs to the Board, vacated the Board’s prior decisions, and provided the limited instruction “to implement the Court’s decision in *SAS*.” Pet App. 145a (hereinafter referred to as “Remand Order”). It is undisputed that the panel did not provide any other specific instructions in the Remand Order. *See* Pet. App. 145a.

On remand, the Board again reviewed the three IPR petitions and concluded again that Petitioner had failed to establish a reasonable likelihood of prevailing on the 14 grounds for which the Board did not previously institute review. Pet. App. 3a-4a. The Board ultimately exercised its discretion to deny institution as to all 17 grounds presented in the three Petitions and, as a result, terminated the IPR proceedings. Pet. App. 4a.

### **C. Federal Circuit Appeal**

Petitioner filed an appeal from the Board’s non-institution decisions, and Aquestive moved to dismiss the appeal on the grounds that the plain language of 35 U.S.C. § 314(d) bars judicial review of

non-institution decisions like the ones that formed the basis of Petitioner’s appeal. Pet. App. 2a, 5a. The same Federal Circuit panel that had remanded the IPRs in the first instance agreed, with the majority noting first that 35 U.S.C. § 314(a) identifies threshold requirements that a petitioner must meet before the Board can institute review. Pet. App. 5a-6a (hereinafter referred to as “Dismissal Order”). The majority then acknowledged that this provision “grants the Director discretion not to institute even when the threshold is met.” Pet. App. 6a, *quoting Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018).

The majority also recognized the requirements of this Court’s *SAS* decision, namely that partial institution decisions are not permitted and that the Board must make “a simple yes-or-no institution choice” when reviewing a petition. Pet. App. 6a, *quoting PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018). The majority also reaffirmed that, regardless of outcome of that choice, “Section 314(d) plainly states that the Patent Office’s decision whether to institute IPR is not appealable.” Pet. App. 7a.

On the question of whether it was permissible for the Board to revisit its original institution decision, the majority recognized both that the plain language of 35 U.S.C. § 318(a) permits dismissal of a review once instituted and that the Board “possess[es] inherent authority to reconsider [its] decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.” Pet. App. 7a, *quoting Medtronic, Inc. v. Robert Bosch*

*Healthcare Sys., Inc.*, 839 F.3d 1382, 1385 (Fed. Cir. 2016). Accordingly, the majority concluded that “[n]othing ‘clearly deprives’ the Board from exercising that inherent, ‘default authority’ here.” Pet. App. 7a, *quoting Medtronic* at 1385-86. The majority confirmed that the Board correctly followed both *SAS* and the original panel remand order, noting that “[i]n following our Remand Order to ‘implement *SAS*,’ the Board corrected its partial institution errors by reviewing its institution decisions and properly exercising its discretion not to institute review at all. Nothing in our Remand Order divested the Board of that discretion.” Pet. App. 7a. The Honorable Pauline Newman dissented from the panel’s Dismissal Order. Pet. App. 11a-16a. Although Judge Newman disagreed that the Board retained discretion to deny institution on remand, she acknowledged that the Remand Order directed the Board only “to implement the Court’s decision in *SAS*.” Pet. App. 11a.

Petitioner filed a request for rehearing and rehearing *en banc*. Pet. App. 126a. The petitions were denied, with a single judge dissenting. Pet. App. 126a. In that lone dissent, Judge Newman again expressed her view that the Remand Order, in instructing the Board “to implement the Court’s decision in *SAS*,” should not be interpreted to cover the Board’s partial institution decision and should require the Board to institute review on all grounds and proceed to a Final Written Decision on that broader review. Pet. App. 133a-134a.

## REASONS FOR DENYING THE PETITION

For two clear reasons, the petition does not merit review by this Court.

*First*, the Federal Circuit applied well-settled law to the procedural facts of this case. There is simply no conflict over the relevant law that would require this Court's intervention. The first question presented in the petition asks whether the judiciary has authority to review a Patent Office decision "refusing to implement its mandate and this Court's precedent." Pet. at i. However, the Federal Circuit exercised review over these questions and found that the PTAB complied with both the *SAS* decision and its earlier mandate. Pet. App. 8a-9a. Petitioner's first question presented is therefore inapplicable to this case. The second question presented in the petition asks whether a petitioner may appeal a decision terminating an instituted IPR, "despite the decision being mislabeled as a nonappealable decision." Pet. at i. But the PTO did not "label" its decision as nonappealable; instead, this was the conclusion reached by the Federal Circuit after finding that "[n]othing in our Remand Order divested the Board" of its discretion to revisit its institution decisions and that the Board on remand "properly exercis[ed] its discretion not to institute review at all." Pet. App. 8a. This procedural history confirms that Petitioner's second question presented is fact-specific and has no little or no connection to the Federal Circuit's opinion.

*Second*, Petitioner's invocation of "due process" and the purported "negation" and "nullification" of judicial review does not amount to a "compelling

reason” that would justify this Court’s review. *See* SUP. CT. R. 10. Unable to point to any legitimate conflict, Petitioner resorts to references to “dangerous” precedent and concerns for future petitioners at the Board. In doing so, Petitioner posits arguments that simply amount to a fact-specific disagreement with the result of its failed IPR attempts. Such a disagreement does not warrant further review by this Court, particularly where the Federal Circuit’s own review on appeal confirmed twice that the Board complied with the original Remand Order.

The petition therefore does not present any issues that would justify this Court’s review and should be denied.

**I. The Questions Presented Involve Only a Fact-Specific Application of Settled Law**

The majority of Petitioner’s arguments are based on the false premise that on remand, the Board disobeyed both the Remand Order and *SAS*. *See* Pet. at 10-24. However, the Federal Circuit’s Dismissal Order contradicts any such assertion and renders further review inappropriate.

Petitioner all but ignores that the very Federal Circuit panel that issued the Remand Order is the same panel that dismissed Petitioner’s appeal following the Board’s issuance of the non-institution decisions on remand. In fact, Petitioner claims that the Board “refuse[d] to comply with [*SAS*] and the Federal Circuit’s remand order.” Pet. at 10. This statement cannot be squared with the Federal Circuit’s own review of the Board’s actions on remand and its resulting decision to dismiss

Petitioner's appeal from those actions. *See, e.g.*, Pet. App. 1a-10a. As the Federal Circuit plainly stated in reviewing the Board's actions on remand:

In this case, the Board initially erred under *SAS* by instituting partial review instead of making yes-or-no institution decisions. In following our *Remand Order* to "implement *SAS*," the Board corrected its partial institution errors by revisiting its institution decisions and properly exercising its discretion not to institute review at all. Nothing in our *Remand Order* divested the Board of that discretion.

Pet. App. 8a.

Contrary to Petitioner's arguments here and in its first question presented, this is not a situation where the Board's conduct went unchecked or unreviewed. Quite the opposite is true. Accordingly, Petitioner's first question presented is not applicable to this case. Here, the Federal Circuit exercised judicial authority over the Board by reviewing the Board's actions to determine whether the Board followed the instructions it had given the Board on remand. The Federal Circuit panel explicitly confirmed that the Board "follow[ed] [the panel's] Remand Order." Pet. App. 8a. In other words, the Dismissal Order confirms that the very panel that issued the Remand Order was satisfied that the Board did in fact comply with that Order. As such, Petitioner's second question presented is also inapplicable to this case because nothing was "misabeled." Petitioner's arguments to the contrary

are inaccurate and further confirm that no further review by this Court is necessary or appropriate.

Petitioner also attempts to compare the Federal Circuit’s Remand Order here with other allegedly “similar remand orders in other cases” (Pet. at 16), but that argument, and the language to which Petitioner cites, is a red herring. Petitioner does not—because it cannot—argue that the final results of those cases contradict the result here or that the resulting body of law flowing from the decisions is in conflict. Petitioner’s arguments are based on the fact-specific language used by the Federal Circuit in each case, which is different from the language used by the panel’s Remand Order in this case. This again confirms that Petitioner’s only complaint is that the Federal Circuit and the Board reached a conclusion—*i.e.*, that denial of institution was appropriate on remand—that Petitioner dislikes. This type of fact-specific disagreement does not give rise to an issue that justifies this Court’s review.

To the extent Petitioner’s arguments regarding the Board’s alleged non-compliance can be read instead as merely an allegation that the Federal Circuit misapplied the holding of *SAS* in its review of the Board’s remand orders, such a reading would likewise fail to establish any issue warranting review by this Court. *See, e.g.*, SUP. CT. R. 10 (“A petition for a writ of certiorari is rarely granted when the asserted error consists of . . . the misapplication of a properly stated rule of law.”). Petitioner does not assert that the Federal Circuit in any way misstated this Court’s holding in *SAS*. Instead, Petitioner’s arguments reveal a mere disagreement with the

Federal Circuit’s conclusion that, under the undisputed (and correctly stated) holding of *SAS*, the Board’s non-institution decisions complied with the Federal Circuit’s Remand Order.

## **II. Petitioner Does Not Raise Any Exceptionally Important Issues Warranting Review**

As the Federal Circuit recognized, the foundation of Petitioner’s appeal boiled down to a disagreement with the Board’s decision not to institute review on any of BDSI’s petitions. Pet. App. 8a (“[Petitioner’s] appeals merely challenge the Board’s determination not to institute review”). The same remains true here with the remaining arguments in the instant petition.

### **A. Petitioner’s Claims of “nullification” and “negation” of Judicial Review Misstate the Record**

Petitioner takes issue with the Board’s non-institution decisions so that it can fashion a non-existent legal issue out of the specific facts of this case. In particular, Petitioner falsely claims that the Federal Circuit’s Dismissal Order would “negate” or “nullify” judicial review. *See* Pet. at 10, 21. Petitioner cites to Judge Newman’s dissent from the Dismissal Order in support of its argument (*see, e.g.*, Pet. at 22, 27), but like Petitioner’s arguments, the dissent is based on the false premise that the Remand Order divested the Board of its discretionary authority to deny institution.

Petitioner claims that the Federal Circuit’s Dismissal Order permits the Board “to terminate any IPR at any stage and for any reason, with no

possibility of judicial review.” Pet. at 24. This false characterization of the Federal Circuit’s Dismissal Order is based on Petitioner’s strained application of the plain language of 35 U.S.C. § 314(d), which clearly states that the Board’s decision whether to institute an inter partes review is a non-appealable one. As an initial matter, there is no dispute here regarding the interpretation of 35 U.S.C. § 314(d), and Petitioner does not assert that there is any conflicting law interpreting that provision in a way that would justify review by this Court. The Federal Circuit correctly stated and applied the plain language of the statute to conclude that where, as here, the Board decides not to institute an IPR, that decision is non-appealable. There is therefore no misinterpretation or misapplication of the statutory constraints that would render necessary any further review by this Court.

Petitioner’s notion of the far-reaching impact of the Federal Circuit’s decision here on future cases is, at best, exaggerated and is, at worst, a misrepresentation of the Federal Circuit’s holding. Fundamentally, following this Court’s *SAS* decision, all institution decisions from the Board will be binary; in other words, the Board will either deny institution in full or it will grant institution in full. *SAS*, 138 S. Ct. at 1355 (holding that when issuing a decision on institution, the Board must make “a binary choice—either institute review or don’t.”). Therefore, to the extent there could have been any reviewable issues, they are now stale because the circumstance of this case will not arise again. The only reason this case has reached its current posture is that it was one of the handful of cases where there

was a remand of an IPR to the Board after *SAS* because of a partial institution decision. There will not be any similar remands in the future because there are no remaining pre-*SAS* institution decisions. In short, the unique posture of this case does not present the kind of issues that would require consideration and clarification by this Court.

As explained above, there *was* judicial review of the Board’s non-institution decisions in this case. And, the result of that judicial review was the Federal Circuit’s explicit confirmation that the Board complied with the directions the panel gave the Board for how to proceed on remand. *See supra* at Section I; Pet. App. 8a. This is the very type of judicial review that Petitioner itself invokes based on this Court’s precedent. *See* Pet. at 23, citing *Oil States Energy Servs., LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018) (“[B]ecause the Patent act provides for judicial review by the Federal Circuit, see 35 U.S.C. § 319, we need not consider whether inter partes review would be constitutional ‘without any sort of intervention by a court at any stage of the proceedings.’”).<sup>1</sup>

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<sup>1</sup> Petitioner also cites to *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345 (Fed. Cir. 2018) only for the proposition that the Federal Circuit has exclusive authority to review other Board decisions “that dispose of an instituted IPR.” Pet. at 25. *Arthrex*, however, does not relate to a non-institution decision. Far from review over a non-institution decision, *Arthrex* concerned the issue of whether a party could appeal from a final adverse judgment entered under 37 C.F.R. 42.73(b).

Because the Federal Circuit exercised judicial review (which it would not normally have under 35 U.S.C. § 314(d)) in concluding that the Board's issuance of revised non-institution decisions on remand complied with its original Remand Order, there is nothing left for this Court to review. And, Petitioner's attempt to sound a false alarm over purported "nullification" and "negation" of judicial review is an attempt to mischaracterize the record to garner this Court's attention. There is no such risk to future cases from the Dismissal Order, and the petition should be denied.

**B. There Are No "Due Process" Issues That Would Justify Review**

Petitioner's final attempt at manufacturing a ground for this Court's review is Petitioner's invocation of "due process." *See* Pet. at 34. However, as with Petitioner's other arguments, this last argument is a regurgitation of the same basic argument with an ill-fitting constitutional moniker. Petitioner raised this same "due process" argument at the Federal Circuit, both in its opposition to the Motion to Dismiss and in its petition for *en banc* review. In both instances, the Federal Circuit was unmoved by the argument and declined even to mention the phrase, let alone give it credence with any analysis. The Federal Circuit's silence on the question of "due process" is telling and further confirms that it does not provide a basis for review by this Court.

As Petitioner concedes, Petitioner's "due process" claim rests on the false premise that Petitioner's rights were violated because "the [Board]

[disregarded] the Federal Circuit’s mandate or judicial precedent.” Pet. at 34. As explained above, the Board did not disregard either the Remand Order or *SAS*, as plainly stated by the Federal Circuit. Also, the Petitioner does not lose due process rights simply by failing to prevail in its years-long campaign to invalidate the ’167 patent before the Board. In fact, Petitioner remains free to raise invalidity challenges in district court proceedings, including the challenges that it raised in its failed IPR petitions. Because this final argument is yet another fact-specific argument without any relation to a question of exceptional importance, there is no basis for this Court to exercise its discretion to review this case.

### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

JOHN L. ABRAMIC  
STEPTOE & JOHNSON LLP  
227 W. Monroe St.  
Suite 4700  
Chicago, IL 60606

JAMIE L. LUCIA  
STEPTOE & JOHNSON LLP  
One Market Plaza  
Spear Tower, Suite 3900  
San Francisco, CA 94105

JAMES F. HIBEY  
ALICE E. LOUGHRAN  
*Counsel of Record*  
STEPTOE & JOHNSON LLP  
1330 Connecticut Ave., N.W.  
Washington, D.C. 20036  
(202) 429-6270

aloughran@steptoe.com

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