

No. 19-1381

---

---

IN THE  
**Supreme Court of the United States**

---

BIODELIVERY SCIENCES  
INTERNATIONAL, INC.,

*Petitioner,*

*v.*

AQUESTIVE THERAPEUTICS, INC.  
FKA MONOSOL RX, LLC,

*Respondent.*

---

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED  
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

---

---

**REPLY BRIEF FOR PETITIONER**

---

---

KIA L. FREEMAN (Bar # 314474)  
*Counsel of Record*  
WYLEY S. PROCTOR (Bar # 312534)  
THOMAS FOLEY (Bar # 312470)  
McCARTER & ENGLISH, LLP  
265 Franklin Street, 14th Floor  
Boston, MA 02110  
(617) 449-6500  
kfreeman@mccarter.com



**RULE 29.6 CORPORATE DISCLOSURE  
STATEMENT**

Petitioner BioDelivery Sciences International, Inc. has no parent corporation, and no publicly held company owns 10 percent or more of its stock.

TABLE OF CONTENTS

	<i>Page</i>
RULE 29.6 CORPORATE DISCLOSURE STATEMENT .....	i
TABLE OF CONTENTS.....	ii
TABLE OF CITED AUTHORITIES .....	iv
INTRODUCTION.....	1
ARGUMENT.....	2
I. THE PRESENTED QUESTIONS POSE UNSETTLED ISSUES OF LAW .....	2
A. The Dismissal Order Raises New Questions About Statutory Limitations on Board Authority in an <i>Inter Partes</i> Review .....	3
B. The Dismissal Order Conflicts With <i>SAS Institute v. Iancu</i> .....	5
II. THE QUESTIONS PRESENT EXCEPTIONALLY IMPORTANT ISSUES THAT WARRANT REVIEW .....	7
A. The Dismissal Order Negates the Procedural Due Process Rights of a Petitioner in an Instituted IPR .....	7

*Table of Contents*

	<i>Page</i>
B. The Federal Circuit’s Dismissal Order, If Permitted to Stand, Impacts All Future IPRs .....	8
CONCLUSION .....	11

TABLE OF CITED AUTHORITIES

	<i>Page</i>
<b>Cases</b>	
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016) . . . . .	3
<i>Medtronic, Inc. v.</i> <i>Robert Bosch Healthcare Sys., Inc.</i> , 839 F.3d 1382 (Fed. Cir. 2016) . . . . .	9
<i>SAS Inst., Inc. v. Iancu</i> , 138 S. Ct. 1348 (2018). . . . .	<i>passim</i>
<i>Thryv, Inc. v. Click-to-Call Technologies, LP</i> , 140 S. Ct. 1367 (2020). . . . .	5
<i>Tokyo Kikai Seisakusho, Ltd. v. United States</i> , 529 F.3d 1352 (Fed. Cir. 2008) . . . . .	9-10
<b>Statutes</b>	
35 U.S.C. § 314(a). . . . .	3
35 U.S.C. § 314(d). . . . .	<i>passim</i>
35 U.S.C. § 315(a). . . . .	8
35 U.S.C. § 315(b). . . . .	8
35 U.S.C. § 316(c). . . . .	7
35 U.S.C. § 317(a). . . . .	5, 7
35 U.S.C. § 318(a). . . . .	5

## INTRODUCTION

After instituting inter partes reviews (IPRs) and issuing final written decisions, does the Patent Trial and Appeal Board have authority to terminate the instituted IPRs over petitioner’s objection—and to unilaterally make that termination nonappealable? In other words, does the Board have unfettered authority to unwind an instituted IPR? The Board exploited that alleged “inherent” authority in decisions on remand. The Federal Circuit ratified the Board’s supposed authority and found that it lacked authority to review the Board’s decisions on remand. But there is no “inherent” authority permitting the Board to circumvent the entire statutory framework for IPRs and to avoid judicial review of that circumvention.

Respondent suggests that the Court should not grant certiorari because the Dismissal Order was decided by the same panel that decided another order. Opp. at 9. But any panel is capable of making a mistake on an issue of law—even after deciding other issues correctly. Petitioner seeks review of the issues of law raised by the Dismissal Order.

Respondent also argues that the Court should not grant certiorari because the Federal Circuit reviewed the Board’s decisions on remand. *See, e.g.*, Opp. at 2, 8, 9-10, 14, 15. As an initial matter, this is factually wrong; the Federal Circuit expressly held that “Section 314(d) *bars* judicial review ... of the Board’s decisions.” Dismissal Order at Appx. 9a (emphasis added). To the extent that the Federal Circuit performed any “review” of the decisions on remand in its order dismissing Petitioner’s appeal for lack of authority to review those decisions, that “review”

is inadequate. In any event, Petitioner seeks review of the Dismissal Order and the Dismissal Order erred on the law.

There can be few IPR issues more important and having broader implications than whether an instituted IPR can be terminated by the Board at any time and at its discretion, without any possibility of appeal. The Federal Circuit's ratification of this alleged Board authority risks depriving every petitioner in an instituted IPR of any procedural due process rights. The consequences of the Dismissal Order reach far beyond appeals of final written decisions in which the Board improperly limited its review to a subset of petition challenges. Under the Dismissal Order, the Board may choose—at any time and at its discretion—not to issue a final written decision.

## **ARGUMENT**

### **I. THE PRESENTED QUESTIONS POSE UNSETTLED ISSUES OF LAW**

Predictably, Respondent argues that the questions presented involve only a fact-specific application of settled law. Opp. § I. Respondent's characterization of the law as "settled" does not make it so. The Dismissal Order at issue in the Petition is precedential because it breaks new legal ground. The Dismissal Order ratifies an "inherent" Board authority to terminate an instituted IPR over the petitioner's objection without reaching a final written decision—even on remand after vacatur of a final written decision. It further ratifies an alleged Board authority to make such a termination decision nonappealable.

**A. The Dismissal Order Raises New Questions About Statutory Limitations on Board Authority in an Inter Partes Review**

This Court has explained that 35 U.S.C. “§ 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.” *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359, (2018) (emphasis added) (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)). Under that paradigm, a decision terminating an instituted IPR is generally appealable. The precedential Dismissal Order at issue in the Petition establishes a different paradigm—a paradigm under which characterization of a decision terminating an instituted IPR as a decision under § 314(a) makes the termination decision nonappealable.

Although this case began like many other IPRs—with Board decisions to institute IPRs including an announcement of improper limitations on the scope of the review—it recently raised new issues of law. On remand, after vacatur of inadequate final written decisions, and over Petitioner’s objection, the Board terminated the instituted IPRs. In doing so, the Board claimed to exercise an inherent discretionary authority to reverse decisions whether to institute inter partes reviews. By labeling the termination decisions as institution decisions under § 314(d), the Board suggested that the decisions on remand should be deemed nonappealable.

Before allowing argument on the merits, the Federal Circuit dismissed Petitioner’s appeal of the Board’s



decisions on remand for lack of jurisdiction. The Dismissal Order is precedential and ratifies a purported inherent Board authority to terminate an instituted IPR over the petitioner's objection, at any time, and without reaching a final written decision. Further, by agreeing that the Board's decisions were non-institution decisions, the Dismissal Order ratifies the Board's assumed authority to make its termination decision nonappealable.

Respondent argues that “[t]here is ... no misinterpretation or misapplication of the statutory constraints that would render necessary any further review by this Court.” Opp. at 13. To the contrary, the fact that the Dismissal Order largely omits any discussion of the express statutory constraints supports review. Relying on two of its own previous decisions and speculation about what Petitioner would have argued if allowed to reach the merits of its appeal, the Federal Circuit waives away the statutory constraints. The lack of statutory analysis is another reason to grant certiorari of the Dismissal Order: a newly-created administrative authority—one supposedly “inherent” and nonappealable—should not be accepted without a thorough analysis of express statutory constraints.

The Dismissal Order does not explain how the Board's alleged nonappealable termination authority is consistent with the statutory scheme for IPRs. For example, the Dismissal Order acknowledges the finality requirement of § 314(d), but does not explain how authority to reverse an institution decision could be consistent with § 314(d)'s requirement that the initial “decision whether to institute an inter partes review ... shall be final ....” The Dismissal Order suggests that the decisions on remand may be

considered dismissals under § 318(a), but does not explain why these “dismissals” under § 318(a) are not appealable. Similarly, it does not explain why the Board has authority to terminate the instituted IPRs over Petitioner’s objection when § 317(a) only allows the Board that authority when no petitioner remains in the IPR. While it recognizes that any inherent authority to reconsider a decision is subject to limitations, the Dismissal Order nonetheless fails to explain why the express statutory limitations do not apply here.

Petitioner asks this Court to review the Dismissal Order’s precedential ratification of an unfettered and nonappealable Board authority to terminate an instituted IPR. *See* Pet. § II. Whether the Board has such a nonappealable authority is a question of law, which the Federal Circuit got wrong. Respondent has identified no factual dispute that could interfere with the resolution of the legal questions presented to this Court.

### **B. The Dismissal Order Conflicts With *SAS Institute v. Iancu***

As the Petition notes, “*SAS [Institute v. Iancu]* held that a petitioner in an instituted IPR is entitled to a complete final written decision.” Pet. at 14 (emphasis omitted); *see also id.* at 5, 13, 21. As this Court recently restated: “*SAS* ... first held that once the agency institutes an inter partes review, it must ‘resolve *all* of the claims in the case.’” *Thryv, Inc. v. Click-to-Call Technologies, LP*, 140 S.Ct. 1367, 1376 (2020) (emphasis original). “*SAS* ... next held that § 314(d) did not bar judicial review of § 318(a)’s application.” *Id.*

Respondent contends that “Petitioner does not assert that the Federal Circuit in any way misstated this Court’s holding in *SAS*.” Opp. at 11. Respondent is simply wrong. The Petition puts the conflict between *SAS* and the Dismissal Order squarely at issue.

As an initial matter, the Dismissal Order misidentifies a corollary of *SAS*’s holding as the holding itself. *See* App. 6a (misstating *SAS*’s holding as “the Patent Office exceeded its statutory authority by limiting its review to fewer than all of the claims challenged in the IPR petitions.”). The Dismissal Order wrongly suggests that *SAS* merely requires a yes-or-no institution decision respecting a petition, which decision is not appealable. *See* App. 6a-9a. If that were true—which it is not—then *SAS* would not conclude that the petitioner “is entitled to a final written decision ....” *SAS*, 138 S.Ct. at 1359.

More importantly, the Dismissal Order effectively rejects *SAS*’s holding. Whereas *SAS* held that a petitioner in an instituted IPR is entitled to a complete final written decision, the Dismissal Order holds the opposite. According to the Dismissal Order, “there is no requirement that once instituted, IPRs must proceed through final written decisions.” App. 7a. The Federal Circuit’s misinterpretation of *SAS* should not remain unchecked.

The Petition explains that the Dismissal Order conflicts with *SAS*—the very decision that led to the remand. *See, e.g.*, Pet §§ I.B.1-2. The Petition explains that the Federal Circuit “rejected *SAS*’s premise that a petitioner in an instituted IPR is normally entitled to a complete final written decision.” *Id.* at 20. It further explains that, under

the Dismissal Order, “the petitioner in an instituted IPR never has the right to a final written decision ....” *Id.* at 22. It warns: “The Dismissal Order creates a precedent that eliminates the reasonable expectation of a final written decision in an instituted IPR.” *Id.* at 22. “In fact, under the Dismissal Order, the PTAB need never issue a final written decision.” *Id.* at 23. In short, the Petition squarely presents the direct conflict between the Dismissal Order and *SAS* as an issue for review.

## **II. THE QUESTIONS PRESENT EXCEPTIONALLY IMPORTANT ISSUES THAT WARRANT REVIEW**

The Federal Circuit’s Dismissal Order ratifies the Board’s exploitation of an alleged “inherent” power to terminate any IPR at any time, without a final written decision and without the possibility of appeal. There can be few IPR issues of greater consequence or broader application. Congress never intended § 314(d) as a loophole to allow the Board to avoid judicial review of decisions terminating instituted IPRs. In allowing the Board to use § 314(d) to avoid appeal, the Dismissal Order risks depriving every petitioner in an instituted IPR of due process rights.

### **A. The Dismissal Order Negates the Procedural Due Process Rights of a Petitioner in an Instituted IPR**

The America Invents Act created an inter partes review process in which a petitioner gains procedural due process rights upon institution of the IPR. *See, e.g.*, 35 U.S.C. § 316(c) (“The ... Board shall ... conduct each inter partes review instituted ....”), § 317(a) (“If no petitioner

remains in the inter partes review, the Office may terminate the review ....”). In *SAS*, this Court recognized that a petitioner gains procedural due process rights when the Board makes the discretionary decision to institute an IPR. *See* Pet. § I.B.1. The Dismissal Order rejects the statutory scheme. By endorsing an unfettered Board authority to terminate an instituted IPR, the Dismissal Order ratifies a new scheme in which an IPR petitioner never gains due process rights. *See* Pet. § II.

Respondent admits the Federal Circuit failed to address the due process issue that Petitioner raised below. Opp. at 15. Nonetheless, Respondent suggests that due process in an IPR cannot be a concern because an IPR petitioner can challenge patent validity in district court litigation. Opp. at 16. But Congress expressly created IPRs to provide successful petitioners an alternative to litigation. *See* 35 U.S.C. § 315(a)-(b). The expectation of due process in district court litigation cannot excuse the Patent Office from its obligation to provide procedural due process in an instituted IPR.

### **B. The Federal Circuit’s Dismissal Order, If Permitted to Stand, Impacts All Future IPRs**

Trying to minimize the consequences of the Federal Circuit’s error, Respondent mischaracterizes this appeal as “a disagreement with the Board’s decision not to institute review on any of BDSI’s petitions.” Opp. at 12. The issue in this appeal is not whether the Board should have instituted Petitioner’s IPRs. The Board *did* institute Petitioner’s IPRs. Opp. at 5 (“Board instituted review[s]”). Rather, the issue is whether a decision terminating an instituted IPR becomes unappealable merely because it

is characterized as a “decision whether to institute” under § 314(d).

Respondent tries to limit the applicability of the Federal Circuit’s erroneous holding to cases in which the Board, contrary to *SAS*, limited its review to only a subset of the petition challenges. *See, e.g.*, Opp. at 13 (arguing that the issues on appeal “are now stale because the circumstances of this case will not arise again.”); *id.* at 14 (“There will not be any similar remands in the future because there are no remaining pre-*SAS* institution decisions.”). But Respondent does not—because it cannot—identify anything in the Dismissal Order limiting the Board’s alleged “inherent authority” to IPRs instituted before *SAS*.

The analysis in the Dismissal Order relies on four points, none of which depends on *SAS* or an improper limitation of the scope of an IPR. First, the Federal Circuit notes that “the Director ... has discretion to not institute review even when the threshold showing issue is met.” Dismissal Order at App. 6a. Second, the court notes that “Section 314(d) plainly states that the Patent Office’s decision whether to institute IPR is not appealable.” Dismissal Order at App. 7a. Third, the court notes that “there is no requirement that once instituted, IPRs must proceed through final written decision.” *Id.* Fourth, the Federal Circuit finds that “administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.” *Id.* (quoting *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1385 (Fed. Cir. 2016) and *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352,

1360 (Fed. Cir. 2008)). None of these points depends on SAS—either directly or indirectly. And on the basis of these four points, the Dismissal Order holds that decisions characterized by the Board as “decisions whether to institute”—even decisions terminating instituted IPRs—are not subject to judicial review. App. 8a-9a.

As explained in the Petition, the Federal Circuit’s reasoning in the Dismissal Order is flawed. A “decision to not institute” is different from a decision terminating an instituted IPR. *See* Pet. at 31-32. Further, while the statute does permit “terminat[ion]” of an instituted IPR, it does not permit termination over the protest of an IPR petitioner. *See id.* at 32-34. Most importantly, the Board has no “inherent” authority to terminate an IPR that was properly instituted and certainly no authority to render that decision unappealable at its own discretion. *See id.* at 17-24, 27-31.

The Federal Circuit’s reasoning, however erroneous, is equally applicable to any instituted IPR. If allowed to stand, the Dismissal Order would give the Board the nonappealable authority to terminate any instituted IPR—regardless of the scope of the Board’s review—by “reconsider[ing]” its institution decision. Nothing in the Dismissal Order limits the Board’s purported “inherent authority” to the underlying facts of Petitioner’s IPRs, to IPRs instituted before SAS, to SAS, or even to cases on remand. In any IPR, and at any time, the Board need merely change its mind.

**CONCLUSION**

For the foregoing reasons, the Court should grant the petition.

Respectfully submitted,

/s/ Kia L. Freeman

KIA L. FREEMAN (Bar # 314474)

*Counsel of Record*

WYLEY S. PROCTOR (Bar # 312534)

THOMAS FOLEY (Bar # 312470)

McCARTER & ENGLISH, LLP

265 Franklin Street, 14th Floor

Boston, MA 02110

(617) 449-6500

kfreeman@mccarter.com