

**Nos. 2019-1643, -1644, -1645
IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

BIODELIVERY SCIENCES INTERNATIONAL, INC.,

Appellant,

v.

AQUESTIVE THERAPEUTICS, INC. FKA MONOSOL RX, LLC,

Appellee.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2015-00165, IPR2015-00168, and IPR2015-00169.

**RESPONSE TO PETITION FOR REHEARING EN BANC
OF ORDER DISMISSING CONSOLIDATED APPEALS
BY AQUESTIVE THERAPEUTICS, INC.**

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CERTIFICATE OF INTEREST

Counsel for appellee Aquestive Therapeutics fka MonoSol Rx, LLC certifies the following:

1. The full name of every party or amicus represented by me is:

Aquestive Therapeutics, Inc. fka MonoSol Rx, LLC

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Not applicable.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Hoffman & Baron – Daniel A. Scola, Jr. and Michael I. Chakansky

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b).

Reckitt Benckiser Pharmaceuticals, Inc., et al. v. BioDelivery Sciences Int'l, Inc., 5:15-cv-00350 (E.D.N.C.)

BioDelivery Sciences Int'l Inc. v. Aquestive Therapeutics, Inc. fka MonoSol Rx LLC, IPR2015-00165, IPR2015-00168 and IPR2015-00169 (P.T.A.B.)

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INTRODUCTION

Appellee Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC (“Aquestive”) opposes Appellant BioDelivery Sciences International Inc.’s (“BDSI’s”) petition for rehearing en banc. The majority correctly applied Supreme Court and Federal Circuit precedent in concluding that BDSI’s appeal must be dismissed. The Patent Trial and Appeal Board (“the Board”) followed the panel’s remand instructions by properly implementing *SAS*, and there is no appellate jurisdiction to review a non-institution decision. BDSI’s invocation of “due process” also fails, and none of its arguments can establish that this is a case of such exceptional importance that requires review by the full Court.

BDSI’s petition for rehearing is based on the incorrect premise that the Board did not comply with the panel’s remand instructions when the Board declined to institute an *inter partes* review. However, the Board *did* comply with the panel’s remand instructions, which directed the Board to implement the Supreme Court’s decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). There can be no dispute that *SAS* requires the Board to make a binary decision between instituting review or not doing so; the Board made that binary choice based on a thorough review and consideration of all 17 grounds presented in BDSI’s petitions. The Board implemented *SAS*, as the panel instructed it to do, by determining first whether BDSI’s petition showed a reasonable likelihood of

success and then by exercising its discretion whether to institute an *inter partes* review (“IPR”). Such a procedure falls squarely within both the strictures of *SAS* and the Board’s authority. Because the Board’s decision *not* to institute an IPR on remand complied with the Supreme Court’s *SAS* decision, the Board’s decision also complied with the panel’s remand instructions.

In dismissing BDSI’s appeal, the majority also correctly applied clear precedent that the Board possesses authority *not* to institute review even when a petitioner meets the threshold requirement for review. As a result, the majority correctly declined to exercise appellate review of the Board’s non-institution decision because such a decision is non-appealable under 35 U.S.C. § 314(d). There is no basis for further en banc consideration, particularly where BDSI’s arguments -- all contrary to well-settled authority -- would remove all discretion from the Board.

BDSI’s remaining arguments, which are based on an improper introduction of additional evidence that was not included in its petition, do not establish a basis for en banc review, notwithstanding BDSI’s invocation of “due process.” The Board complied with 35 U.S.C. § 314(a) by analyzing the evidence BDSI presented *in its petition* and, based on that analysis, decided that *inter partes* review was not appropriate on remand. The Board did not violate due process by declining to consider improper extrinsic evidence any more than the majority did

so by declining to exercise jurisdiction over BDSI's improper appeal. Accordingly, the petition for rehearing should be denied.

BACKGROUND

Aquestive is the assignee of U.S. Patent No. 8,765,167 (“the ’167 Patent”), which is the patent BDSI challenged in the three IPR Petitions that led to this appeal. BDSI filed its IPR Petitions more than five years ago, on October 28, 2014. In its first consideration of BDSI's Petitions, the Board concluded that the majority of the 17 grounds BDSI presented did not meet the threshold level for review and as a result, instituted review on only three grounds. The Board ultimately sustained the patentability of the ’167 Patent based on those three instituted grounds.

While BDSI's first appeal from that patentability decision was pending in this Court, the Supreme Court issued its *SAS* decision. The panel then granted BDSI's motion to remand to the Board, with instructions “to implement the Court's decision in *SAS*.” *BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018) (“Remand Order”).

On remand, the Board reviewed BDSI's three Petitions and concluded again that BDSI had failed to establish a reasonable likelihood of prevailing on the 14 grounds for which the Board did not previously institute review. The Board

ultimately exercised its discretion to deny institution as to all three Petitions, and terminated the proceedings.

BDSI again filed an appeal from the Board's non-institution decision, and Aquestive moved to dismiss the appeal on the grounds that 35 U.S.C. § 314(d) bars judicial review of the Board's non-institution decision. The majority agreed, noting first that 35 U.S.C. § 314(a) identifies threshold requirements that a petitioner must meet before the Board can institute review. Slip Op. at 5. The majority then acknowledged that this provision "grants the Director discretion not to institute even when the threshold is met." *Id.*, quoting *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018). The majority also recognized the requirements of the Supreme 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. *Id.* at 6, 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."

The majority rejected BDSI's argument that the Board was required to institute on all grounds and all claims simply because there was at least one ground for which the threshold showing for review was met. 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.” Slip Op. at 6, quoting *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1385. Accordingly, the majority concluded that “[n]othing ‘clearly deprives’ the Board from exercising that inherent, ‘default authority’ here.” *Id.*, 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.” *Id.* at 7.

LEGAL STANDARD

Pursuant to Federal Rule of Appellate Procedure 35, rehearing en banc is typically “not favored” and is appropriate only where “necessary to secure or maintain uniformity of the court’s decision; or [where] the proceeding involves a question of exceptional importance.” Fed. R. App. P. 35(a).

ARGUMENT

BDSI’s petition for en banc rehearing should be denied. There is no error or inconsistency in how the majority applied Supreme Court and Federal Circuit precedent on institution decisions in dismissing BDSI’s appeal. This is also not a

case that presents any question of “exceptional importance” requiring the Court’s full review.

I. THE BOARD FOLLOWED *SAS* AND THE PANEL’S INSTRUCTIONS ON REMAND

BDSI’s first argument for rehearing rests on the faulty premise that the Board did not comply with the panel’s instructions on remand to implement the Supreme Court’s *SAS* decision. Pet. at 10-12. Because the Board did comply with *SAS*—and therefore necessarily also complied with the panel’s instructions—BDSI’s petition can be denied on this basis alone.

The majority summarized the Board’s remand actions as follows:

Here, the Board’s orders on remand modifying its previous institution decisions constitute the Board’s (1) determination of whether the information presented in the petition shows that there is a reasonable likelihood of success with respect to at least 1 of the claims challenged, and (2) exercise of its discretion whether to institute IPR.

Slip Op. at 8. This summary matches precisely with the commands articulated by the Supreme Court in *SAS*, and thus cannot form the basis for additional review of the Board’s action on remand. Under *SAS*, the Board only exceeds its statutory authority by limiting its review to fewer than all challenged claims if the Board determines that review is appropriate. *SAS*, 138 S. Ct. at 1359-60. As the majority correctly pointed out, the Supreme Court’s ruling establishes that “[Section] 314 ‘indicates a binary choice—either institute review or don’t.’” Slip Op. at 5, quoting *SAS* at 1355.

As the majority correctly found, the Board on remand here made a binary choice after a complete review of BDSI's Petitions. Specifically, the Board: (1) adopted the analysis provided in its Institution Decisions for previously considered, uninstituted grounds; (2) conducted a complete analysis of BDSI's Petitions for those grounds on which the Board did not previously consider (e.g., contingent arguments); (3) reconsidered its analysis of BDSI's Petitions for two grounds on which the Board did previously institute review; and (4) exercised its discretion to deny institution because "the overwhelming majority of unpatentability grounds" did not meet the standard for review. Appeal No. 19-1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00165, at 7, 13, 28; Appeal No. 19-1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00169, at 6, 37; *see also* Appeal No. 19-1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00168, at 8, 31 (referring to "the majority of unpatentability grounds").

BDSI incorrectly insists that the Board "rejected the reasoning of SAS." Pet. at 10. According to BDSI, because the Board found that there were some grounds for which the standard for review was met, the Board was required to institute review on all grounds. Pet. at 10-11. However, the majority correctly rejected this argument based on Federal Circuit precedent holding that the Board "has discretion to not institute review even when the threshold showing is met." Slip Op. at 5,

citing *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018).

Contrary to BDSI's argument, the majority correctly applied *SAS* in concluding that the Board's review complied with Supreme Court precedent. Accordingly, this is not a case where rehearing is necessary to correct some error or inconsistency in application of the Court's precedent. The majority correctly applied precedent, which clearly permits the Board's actions on remand.

II. THERE IS NO BASIS FOR FURTHER REVIEW OF THE BOARD'S NON-INSTITUTION DECISIONS

As the majority recognized, the underlying basis for BDSI's appeal and ultimately its petition boils down to a disagreement with the Board's decision to not institute review on any of BDSI's petitions. Slip Op. at 7 (“[BDSI’s] appeals merely challenge the Board’s determination *not* to institute review”) (emphasis in original). No rehearing is appropriate here because the majority was correct to dismiss BDSI's appeal in light of clear precedent regarding the Board's discretion on institution decisions and the non-appealability of such decisions. In fact, granting BDSI's petition could lead to removal of all Board discretion when deciding whether to institute review, a result which does not find any support in this Court's precedent.

First, precedent is clear that the Board possesses the discretion to decline review, even where there is a showing of a reasonable likelihood of success with

respect to at least one claim. As this Court has made clear, “[t]he Director bears the political responsibility of determining which cases should proceed. While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons . . .” *Saint Regis*, 896 F.3d at 1327, citing *Wi-Fi One*, 878 F.3d at 1372; *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (date) (“The Patent Office’s decision to initiate inter partes review is ‘preliminary,’ not ‘final.’ And the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”) (internal citations omitted).

Second, it is well established that the Board’s decision to not institute review is *not* an appealable decision. As 35 U.S.C. § 314(d) dictates, the Board’s decision whether to institute review is not an appealable decision. *Cuozzo*, 136 S. Ct. at 2139. The non-appealability of such a decision applies equally where—like here—the decision is the result of the Board’s reconsideration of an earlier decision in favor of institution. *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1312 (Fed. Cir. 2015) (holding that the statutory language barring judicial review of institution decisions “is not limited to an *initial* determination to the exclusion of a determination on reconsideration”) (emphasis in original). The majority correctly applied this string of precedent, compared the Board’s remand decisions with those in *Medtronic*, and therefore “strained to describe these decisions to modify the Board’s previous institution decisions and deny institution on remand as anything

but a determination . . . whether to institute proceedings.” Slip Op. at 7, quoting *Medtronic*, 839 F.3d at 1386 (internal quotations omitted).

As a result, because the Board’s remand decisions amount to decisions on institution, the majority was correct to decline to undertake appellate review. There is no basis for any further review en banc.

III. BDSI’S DUE PROCESS RIGHTS WERE NOT VIOLATED BY THE BOARD’S THOROUGH REVIEW OF BDSI’S PETITION ON REMAND

In the absence of any need for the Court to correct an application of precedent, BDSI attempts to invoke “due process.” Its arguments are not only insufficient to justify further review, but they are also based in part on untimely, improper evidence.

BDSI first cites to the Board’s practice in other remanded review proceedings to argue that its rights were violated because the Board did not proceed in the same manner in this case. Pet. at 15. Although BDSI is correct that the Board “did not dispute” the facts of those other cases, the Board has already addressed the fundamental differences between the instant case and those earlier reviews based on BDSI’s failure to meet the threshold for review on the overwhelming majority of the presented grounds. *See, e.g.*, Appeal No. 19-1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00165, at 7, 13, 28; Appeal No. 19-1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00169, at 6, 37; *see also* Appeal No. 19-

1643, Dkt. 6-2, PTAB Remand Dec. IPR 2015-00168, at 8, 31 (referring to “the majority of unpatentability grounds”). BDSI does not, because it cannot, cite to any binding authority that would require the Board to institute review under these circumstances. Accordingly, the Court need not review the majority’s dismissal order, which correctly held that the Board’s actions were permissible under controlling precedent.

Moreover, BDSI has no “right” to have an IPR initiated in the first place. Even where review is instituted, the Board can “dismiss[]” an instituted IPR before reaching any decision on the merits. 35 U.S.C. § 318(a) (“If an inter partes review is instituted *and not dismissed under this chapter* [Chapter 31], the [Board] shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner”). To the extent any rights have been violated as a result of BDSI’s challenges to the ’167 Patent, it is Aquestive that has suffered, not BDSI. BDSI’s years-long attempts to attack the ’167 Patent through IPR proceedings, including this last-ditch effort for en banc review, have crippled Aquestive’s ability to enforce its patent rights against BDSI’s ongoing infringement. *See* Appeal No. 19-1643, Dkt. 6-1 at 5 (summarizing parallel infringement actions that have been stayed as a result of the IPR proceedings). In this case, the panel’s original Remand Order permitted the Board to evaluate BDSI’s Petitions to determine whether or not to institute review under *SAS*, putting

BDSI back in the position it was in when it filed those Petitions. *BioDelivery*, 898 F.3d at 1210. Because the Board concluded, based on BDSI's original petitions, not to institute review, those decisions did not violate any of BDSI's rights, due process or otherwise.

Finally, BDSI improperly points to extrinsic "evidence proffered on remand" to argue that if the Board had instituted review, the ultimate result could have been different. Pet. at 17. That evidence, which was not included in BDSI's Petitions, was submitted to the Board for the first time on remand in response to the Board's request for briefing on whether the Board should vacate its original institution decisions. *Id.* Most importantly, it would be improper for this Court to consider BDSI's extrinsic evidence because the only decision in question is the Board's decision not to institute review. Although BDSI characterizes the Board's decision as "based on selected evidence" (Pet. at 17), the Board correctly followed the statutory requirement to determine whether the threshold requirements were met based on "the information presented in the petition." 35 U.S.C. § 314(a). The Board thoroughly reviewed BDSI's petitions, and the evidence presented in those petitions, and ultimately concluded that review was not appropriate in this case. Just because the Board declined to consider evidence outside of the petition does not mean that any due process rights were violated. Similarly, just as BDSI's rights were not violated by the Board, its rights could not have been violated by the

majority's dismissal of BDSI's improper appeal. Accordingly, there is no basis for an en banc review of that decision.

CONCLUSION

Because the majority correctly applied precedent in its dismissal of BDSI's appeal and because BDSI has not established that this case presents any question of exceptional importance, the Court should deny BDSI's petition for en banc review.

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CERTIFICATE OF COMPLIANCE

Counsel for appellees certify that the brief contained herein has a proportionally spaced 14-point typeface, and contains 2,852 words, based on the “Word Count” feature of Microsoft Word, including footnotes and endnotes. Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b), this word count does not include the words contained in the Certificate of Interest, Certificate of Filing and Service, Table of Contents, Table of Authorities, and Statement of Related Cases.

Dated: November 1, 2019

Respectfully submitted,

/s/ John L. Abramic

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that I electronically filed the foregoing document using the Court's CM/ECF filing system on November 1, 2019. All counsel of record were served via CM/ECF on November 1, 2019.

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