

Nos. 2019-1643, -1644, -1645

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

**PETITION FOR REHEARING *EN BANC* OF
ORDER DISMISSING CONSOLIDATED APPEALS BY
BIODELIVERY SCIENCES INTERNATIONAL, INC.**

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September 30, 2019

CERTIFICATE OF INTEREST

Counsel for Appellant BioDelivery Sciences International, Inc. hereby certifies the following:

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

BioDelivery Sciences International, Inc.

2. The name of the real party in interest represented by me is:

BioDelivery Sciences International, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party 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 nor will not enter an appearance in this case) are:

The following law firms and counsel also appeared on behalf of Appellant/Petitioner in the prior appeal and/or the underlying inter partes reviews: Danielle L. Herritt; Deborah M. Vernon; Lee C. Bromberg; and Erik P. Belt; Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; Cora R. Holt; Howard W. Levine; Thomas J. Sullivan; Charles E. Lipsey; and Jennifer Swan.

Dated: September 30, 2019

Respectfully submitted,

/s/ Kia L. Freeman

Kia L. Freeman

McCarter & English, LLP

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Parties

BioDelivery Petitioner /Appellant BioDelivery Sciences International, Inc.

Aquestive Patent Owner /Appellee Aquestive Therapeutics, Inc. fka MonoSol Rx, LLC

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IPR2015-00168-DOR Decision on Remand in IPR2015-00168, Paper 88
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Terms

PTAB or Board Patent Trial and Appeal Board

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..... 898 F.3d 1205, 1209 (Fed. Cir. 2018)

USPTO United States Patent and Trademark Office

STATEMENT OF COUNSEL

Based on my professional judgment, I believe that the order dismissing Appellant/Petitioner's consolidated appeals of the Patent Trial and Appeal Board's (PTAB's) decisions on remand of the underlying *inter partes* reviews (IPRs)—before argument on the merits—requires an answer to one or more of the following precedent-setting questions of exceptional importance:

1. Whether the Court has authority to review the PTAB's final decision in a remanded IPR for compliance with a remand order—regardless of the PTAB's characterization of its decision?
2. Whether the Court's remand order supplants the PTAB's alleged inherent discretionary authority to reverse its lawful institution of IPRs on remand?
3. Whether a petitioner has a right to argue the merits of its appeal of the PTAB's final disposition of remanded IPRs when the PTAB refused to provide petitioner due process, acted arbitrarily, or otherwise exceeded its authority?

The panel majority found that the PTAB may ignore the Court's remand order. And the majority incorrectly held that the Court is barred from considering the merits of an appeal of decisions in remanded IPRs. Nevertheless, the Court has not only the power, but also the obligation, to ensure that an IPR proceeds in

accordance with the law. The Court must be able to curb PTAB abuses in instituted IPRs. The full Court should reverse the panel majority's divestiture of the Court's authority.

Based on my professional judgment, I also believe that the precedential panel majority Order dismissing Appellant/Petitioner's consolidated appeals is contrary to *SAS Institute v. Iancu*, 138 S.Ct. 1348 (2018); 35 U.S.C. § 144; and *BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. et al.*, 898 F.3d 1205 (Fed. Cir. 2018).

/s/ Kia L. Freeman

Attorney of Record for Petitioner / Appellant,

BioDelivery Sciences International, Inc.

ARGUMENT IN SUPPORT OF REHEARING

I. INTRODUCTION

Patent Owner’s motion to dismiss this appeal raised a fundamental question: whether the PTAB has an inherent, discretionary power to negate the Court’s authority. The panel majority’s dismissal order answered that question “yes.” Respectfully, the majority was wrong.

In BioDelivery’s prior consolidated appeals, the Court vacated “final written” decisions that did not satisfy the minimum statutory requirements under *SAS* and remanded. According to the dissent, the remand order entitled BioDelivery to final written decisions on the full merits of the previously instituted IPRs. *See* Slip Op. at 5 (Newman, J., dissenting). But on remand, “the PTAB held that it would be inefficient and expensive to implement the Supreme Court’s [*SAS*] decision.” *Id.* at 2 (dissent). At Patent Owner’s urging, and over BioDelivery’s objections, the PTAB “withdr[e]w its initial acceptance and all ensuing proceedings as if they never occurred, and negate[d the] *Remand Order.*” *Id.* at 2 (dissent). BioDelivery appealed the PTAB’s remand decisions, but the majority granted Patent Owner’s motion to dismiss the consolidated appeals. Thus, BioDelivery continues to be deprived of an opportunity to be heard on the merits of its challenges.

The order dismissing the consolidated appeals wrongly held that “[s]ection 314(d) bars judicial review” Slip op. at 8, citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016). But “nothing in § 314(d) or *Cuozzo* withdraws [the court’s] power to ensure that an [IPR] proceeds in accordance with the law’s demands.” *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359. This Court must be able to determine whether PTAB decisions in *instituted* IPRs comply with court orders or exceed the PTAB’s authority. BioDelivery should be allowed to argue the merits of its appeals.

II. BACKGROUND

This case arises from the institution of three IPRs, based on BioDelivery’s petitions, each challenging different subsets of claims of U.S. Pat. No. 8,765,167 on multiple grounds. The PTAB improperly excluded petition challenges from the scope of each of the three instituted IPRs, and then issued “final written” decisions that failed to address all of the petition challenges, BioDelivery appealed the “final written” decisions that BioDelivery had not proven unpatentability. And the USPTO Director intervened to modify the decisions’ reasoning.

While BioDelivery’s consolidated appeals were pending, the Supreme Court decided *SAS*—holding that 35 U.S.C. § 318(a) requires a final written decision to address every claim challenged in the underlying petition. *See* 138 S.Ct. at 1359-60. Shortly thereafter, the Court decided *PGS Geophysical AS v. Iancu*, finding

that, although its requirements may be waived, 35 U.S.C. § 318(a) requires a final written decision to address every patentability challenge in the underlying petition. *See* 891 F.3d 1354, 1359-60 (Fed. Cir. 2018). In view of *SAS* and *PGS*, under § 318(a), all of the final written decisions at issue in BioDelivery’s appeals were incomplete.

By motion, BioDelivery “expressly s[ought] the benefit of decisions that satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*.” *Mot. to Terminate and Remand, BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutix, Inc. et al.*, CAFC Appeal Nos. 17-1265, -1266, -1268, Dkt. 91, (June 19, 2018), at 10. Patent Owner and the USPTO Director opposed, arguing that BioDelivery had waived its right to seek *SAS*-based relief and that the motion was untimely. Finding the motion timely and no waiver, this Court “agree[d] that *SAS* requires institution on all challenged claims and all challenged grounds.” *BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutix, Inc. et al.*, 898 F.3d 1205, 1209 (Fed. Cir. 2018) (hereinafter “Remand Order”). This Court vacated the final written decisions as incomplete. *Id.* at 1210. It also declined Patent Owner’s request to decide the merits of the appeal of the incomplete decisions. *Id.* Finally, the Court remanded the IPRs and ordered the PTAB to implement the Supreme Court’s holding in *SAS*. *Id.* at 1210.

On remand, the PTAB should have expanded the scope of the instituted IPRs to encompass all challenged claims and all petition challenges—as *SAS*, *PGS*, and the Remand Order required. But the PTAB did not allow further argument or evidence on the merits of BioDelivery’s petition challenges. The PTAB did not issue final written decisions that complied with § 318(a). Instead, against BioDelivery’s protest, the PTAB issued “Decisions on Remand” that terminated the IPRs. BioDelivery appealed.

After Patent Owner filed identical motions to dismiss in each of BioDelivery’s three appeals, the Court consolidated the appeals and stayed briefing on the merits. Dkt. 15. Patent Owner argued that “[BioDelivery]’s appeal of a [PTAB] decision denying institution after reconsidering its initial institution decision falls outside this Court’s jurisdiction and is barred from review by 35 U.S.C. § 314(d).” Mot. to Dismiss, Dkt. 6-1 (March 20, 2019), at 9. A divided panel dismissed BioDelivery’s appeals before argument on the merits.

The Patent Owner’s motion to dismiss presents the question whether the PTAB must comply with remand orders. Slip op. at 2-3 (Newman, J., dissenting). The dissent opines that, in the remand decisions, the PTAB purported to exercise a nonexistent discretionary authority to supplant the Court’s Remand Order.

“The obligation to comply with a remand order is beyond debate.” *Id.* at 3 (dissent, citing authority). “Precedent illustrates this rule as followed by agencies

and courts, without quibble.” *Id.* (dissent). Indeed, “actions on remand should not be inconsistent with either the letter or the spirit of the mandate.” *Id.* at 4 (dissent, citing authority). *SAS* itself directs that “the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.” 138 S.Ct. at 1355.

Section 144 assigns this Court the obligation to review PTAB decisions. It also provides that this Court’s “mandate and opinion ... shall govern the further proceedings” 35 U.S.C. § 144. As the Supreme Court recognized, “[t]he word ‘shall’ generally imposes a *nondiscretionary* duty.” *SAS*, 138 S.Ct. at 1354 (emphasis added). “Nonetheless, the PTAB declined to execute [this Court’s] *Remand Order*.” Slip op. at 4 (dissent).

Deciding all of the challenges raised in BioDelivery’s petitions “would have required the [PTAB] to conduct full trial proceedings on all challenges, including supplemental briefing, additional discovery, and further oral argument.” *Id.* at 7 (majority). “On remand, the PTAB held that it would be inefficient and expensive to implement the Supreme Court’s decision.” *Id.* at 2 (dissent). So “[i]nstead, [acting on an alleged discretionary authority,] the PTAB withdrew all of its actions as to these three IPRs.” *Id.* (dissent).

The dismissal order exacerbated the PTAB’s error. It wrongly held the PTAB “can ... negate [this Court’s] *Remand Order*.” *Id.* at 2 (dissent); *see also id.*

at 7 (majority) (“Nothing in our *Remand Order* divested the [PTAB] of that discretion.”). The dissent explained: “[t]he PTO’s action in response to our *Remand Order* fails not only the Supreme Court’s [SAS] requirement, but the PTO’s assignment under the America Invents Act to resolve certain validity issues by agency IPR proceeding.” *Id.* at 6.

III. THE DISMISSAL ORDER AGGRAVATES THE FAILURE TO FOLLOW SAS AND THE REMAND ORDER.

“Much as in the civil litigation system it mimics, in an inter partes review the petitioner is master of its complaint and *normally entitled to judgment* on all the claims it raises, not just those the decisionmaker might wish to address.” *SAS*, 138 S.Ct. at 1355 (emphasis added). Even before *SAS*, this full Court agreed that, “[i]f the Director determines to institute IPR, in most cases, the [PTAB] *must* ‘issue a final written decision’” *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1368 (Fed Cir. 2018) (*en banc*) (emphasis added). In *SAS*, the Supreme Court held that the petitioner “*SAS is entitled to a final written decision addressing all of the claims it has challenged ... and remanded [the review] for further proceedings consistent with th[at] opinion.*” 138 S.Ct. at 1359-60 (emphasis added).

By motion in its previous appeals, BioDelivery “expressly s[ought] the benefit of decisions that satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS*” Mot. to Terminate and Remand, CAFC Appeal Nos. 17-

1265, -1266, -1268, Dkt. 91, (June 19, 2018), at 10. BioDelivery “moved to remand the appeals based on *SAS*’s requirement that IPR proceedings *must proceed* in accordance with or in conformance to the petition, including each claim challenged and the grounds on which the challenge to each claim is based.” Slip Op. at 2-3 (internal quotations and citations omitted) (emphasis added). The Remand Order granted BioDelivery’s motion, vacated the “final written” decisions,¹ and remanded the underlying reviews “to implement the Court’s decision in *SAS*.” 898 F.3d at 1210.

The circumstances that led to the Remand Order are analogous to the circumstances that formed the basis for the Supreme Court’s *SAS* holding. Like the petitioner in *SAS*, BioDelivery “d[id] not seek to challenge the Director’s conclusion that it showed a ‘reasonable likelihood’ of success sufficient to warrant ‘institut[ing] an inter partes review.’” *SAS*, 138 S.Ct. at 1359. Instead, like the petitioner in *SAS*, BioDelivery “contend[ed] that the Director exceeded his statutory authority by limiting the review to fewer than all of the claims ...

¹ On remand, the PTAB disputed the reason for the vacatur, restated reasoning from the vacated decisions in new decisions, and terminated the IPRs. It stated: “Petitioner already received the benefit of our Decision to Institute in that we conducted a trial and issued a Final Decision.” IPR2015-00165-DOR at 10. The remand decisions could be interpreted as an effort to flout the Remand Order and effectively reestablish the vacated decisions.

challenged” (*id.* at 1359) and petition challenges. Accordingly, as the dissent found, and like the petitioner in *SAS*, BioDelivery is entitled to final written decisions addressing all of its petition challenges. *See Slip op.* at 5 (dissent).

The Remand Order called for “remand procedures” to implement *SAS*. 898 F.3d at 1210. Again, *SAS* held that the petitioner “*is entitled* to a final written decision addressing all of the claims it has challenged ... and remanded for further proceedings consistent with th[at] opinion.” *SAS*, 138 S.Ct. at 1359-60 (emphasis added). The Remand Order “agree[d] that *SAS* requires institution on all challenged claims and all challenged grounds.” 898 F.3d at 1209. Nonetheless, the PTAB denied BioDelivery the procedures necessary to gain the benefit of complete final written decisions. *See IPR2015-00165-DOR* at 28; *IPR2015-00168-DOR* at 8; *IPR2015-00168-DOR* at 37. Accordingly, the PTAB failed to follow *SAS* and the Remand Order.

Further, the PTAB rejected the reasoning of *SAS*. First, despite acknowledging its previous determination that each petition satisfied the threshold for institution (*see IPR2015-00165-DOR* at 6; *IPR2015-00168-DOR* at 9; *IPR2015-00169-DOR* at 19), the PTAB repeated reasoning from its vacated decisions to find no likelihood of prevailing. But *SAS* found that “[o]nce th[e] single claim threshold is satisfied, it doesn’t matter whether the petitioner is likely to prevail on any *additional* claims.” *SAS*, 138 S.Ct. at 1356.

Second, “the PTAB held that it would be inefficient and expensive to implement [SAS].” *See* Slip op. at 2 (Newman, J., dissenting). But SAS rejected the USPTO Director’s argument that the PTAB could avoid obligations it deemed overly burdensome. *See SAS*, 138 S.Ct. at 1357-58 (“Congress’s prescribed policy here is clear: the petitioner in an inter partes review is entitled to a [final written] decision on all the claims it has challenged.”).

Finally, the PTAB relied on the alleged inherent discretionary authority to reconsider and override petitioner entitlement. *See* IPR2015-00165-DOR at 9-10; IPR2015-00168-DOR at 25-27; IPR2015-00169-DOR at 9. But SAS rejected the Director’s alleged discretionary authority to override a petitioner entitlement. *See, e.g., SAS*, 138 S.Ct. at 1357 (“In all these ways, the statute tells us that the petitioner’s contentions, *not the Director’s discretion*, define the scope of the litigation all the way from institution through to conclusion.”) (emphasis added).

Rather than ensure that the PTAB followed it, the majority disputed the Remand Order. The Remand Order recognized that SAS “held that if the Director institutes review proceedings, the PTAB review *must proceed* in accordance with or in conformance to the petition, including each claim challenged and the grounds on which the challenge to each claim is based.” 898 F.3d at 1207 (internal quotations and citations omitted) (emphasis added). The majority recognized that the Remand Order granted BioDelivery’s “mo[tion] to remand the appeals based

on *SAS*'s requirement that IPR proceedings *must proceed* in accordance with or in conformance to the petition, including each claim challenged and the grounds on which the challenge to each claim is based." Slip Op. at 2-3 (internal quotations and citations omitted) (emphasis added). Nonetheless, contrary to the Remand Order, the majority found "there is no requirement that once instituted, IPRs must proceed through final written decisions." *Id.* at 6.

The majority also failed to follow *SAS* itself. *SAS* explained "nothing in § 314(d) or *Cuozzo* withdraws [the Court's] power to ensure that an inter partes review proceeds in accordance with the law's demands." *SAS*, 138 S.Ct. at 1359. In contrast, the majority, citing *Cuozzo*, held that "[s]ection 314(d) bars judicial review" Slip op. at 8. The majority's justification for not ensuring that the PTAB followed the law divests the Court of its power to ensure that any review follows the law—contrary to *SAS*.

In sum, the majority failed to follow *SAS* and the Remand Order, and thereby condoned and aggravated the PTAB's failure to follow *SAS* and the Remand Order.

IV. THE COURT HAS FULL AUTHORITY TO REVIEW AN APPEAL OF THE REMAND DECISIONS ON THE MERITS.

The Court has the full authority to review appeals of PTAB decisions on remand. The PTAB's characterization of its remand decisions cannot bar review. And 35 U.S.C. § 314(d) does not apply to BioDelivery's appeals.

Without allowing argument on the merits, the panel majority wrongly characterizes these appeals as “merely challeng[ing] the [PTAB]’s determination *not* to institute review.” Slip op. at 7. Based on that mischaracterization, and an analogy to *Medtronic, Inc. v. Robert Bosch Healthcare Systems, Inc.* and *GTNX, Inc. v. INTTRA, Inc.*, the majority concluded that these consolidated appeals were not reviewable. *Id.* at 7. The majority held: “[s]ection 314(d) bars judicial review” *Id.* at 8.

But the circumstances that justified denying review in *Medtronic* and *GTNX* do not apply here. For example, the petitioners in *Medtronic* and *GTNX* both withheld information that implicated a statutory limit on the PTAB’s authority. *See Medtronic*, 839 F.3d 1382, 1383-84 (Fed. Cir. 2016) (petitioner withheld fact that it was a proxy for a subsidiary served with an infringement action more than a year early, which implicated the § 315(b) bar); *GTNX*, 789 F.3d 1309, 1311 (Fed. Cir. 2015) (petitioner withheld fact that it filed civil action challenging the patent’s validity before the date it filed the petition, which implicated the § 325(a)(1) bar). In both *Medtronic* and *GTNX*, the PTAB vacated decisions in which it had been fooled into instituting IPRs, in violation of a statutory bar. *See Medtronic*, 839 F.3d at 1383-84; *GTNX*, 789 F.3d at 1310.

BioDelivery’s appeals present issues that were not raised in *Medtronic* or *GTNX*. Unlike *Medtronic* and *GTNX*, the decisions at issue in BioDelivery’s

appeals are governed by a Remand Order. Without allowing argument on the merits, the majority concluded “[n]othing ... divested the [PTAB] of ... discretion.” Slip op. at 7. BioDelivery seeks to remedy the PTAB’s action in deliberate excess of explicit statutory authority.

“Enforcing statutory limits on agency’s authority to act is precisely the type of issue that courts have historically reviewed.” *Wi-Fi One*, 878 F.3d at 1374. The Supreme Court found “§ 314(d) precludes judicial review only of the Director’s *initial* determination under § 314(a)” *SAS*, 138 S.Ct. at 1359 (emphasis added); *contra* Slip. Op. at 7 (majority finding § 314(d) “is not limited to an *initial* determination”). “[N]othing in § 314(d) or *Cuozzo* withdraws [the court’s] power to ensure that an inter partes review proceeds in accordance with the law’s demands.” *SAS*, 138 S.Ct. at 1359. In other words, the Court has full authority to review an appeal of the Remand Decisions on the merits.

V. BIODELIVERY WAS ARBITRARILY DENIED DUE PROCESS TWICE BY THE PTAB AND THEN AGAIN BY THE MAJORITY

The Remand Order vacated the “final written” decisions in view of *SAS* because the PTAB’s improper limitation of the scope of the IPRs had deprived BioDelivery of due process. The Remand Order called for “remand procedures” to implement *SAS*. 898 F.3d at 1209. *SAS* ordered “further proceedings” consistent with the opinion that the petitioner is entitled to a final written decisions addressing all of the claims it has challenged. 138 S.Ct. at 1359-60.

The remand decisions concluded that the further proceedings required by SAS would be overly burdensome and so instead terminated BioDelivery's IPRs. *See* IPR2015-00165-DOR at 28; IPR2015-00168-DOR at 8; IPR2015-00168-DOR at 6, 37; *see also* Slip Op. at 2 (Newman, J., dissenting). In other words, the remand decisions *again* deprived BioDelivery of due process.

BioDelivery's second denial of due process arbitrarily violated USPTO policy and practice. Before the remand decisions, the PTAB disclosed "[USPTO] policy ... *precluding termination* of a partially instituted proceeding in response to SAS" *ESET, LLC et al v. Finjan, Inc.*, IPR2017-01738, Paper 28, 2018 WL 3854167 *4 (PTAB 2018) (emphasis added). The remand decisions violated that policy, but did not dispute its existence. *See, e.g.*, IPR2015-00165-DOR at 11 (procedurally distinguishing *ESET*). In accordance with that policy, before the remand decisions, the PTAB had consistently ordered the expansion of the scope of reviews remanded in view of SAS to include non-instituted claims and grounds. *See Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2015-01781, Paper 57; *Nestle Purina PetCare Company v. Oil-Dri Corp.*, IPR2015-00737, Paper 45; *Adidas AG v Nike, Inc.*, IPR2016-00921, Paper 23; *Baker Hughes Oil Field Operations, Inc. v. Smith Int'l, Inc.*, IPR2016-01452, Paper 33; *Ulthera, Inc. v. DermaFocus LLC*, IPR2016-01459, Paper 34 (all PTAB 2018 decisions amending institution decision on remand to include all challenged claims and grounds). Before the remand

decisions, the PTAB simply expanded the scope of remanded IPRs as required by SAS. In other words, the remand decisions here violated USPTO policy and practice in view of SAS.

The majority arbitrarily denied BioDelivery the opportunity to argue the merits of its appeals. They wrongly assumed that BioDelivery would “merely challenge the [USPTO]’s determination not to institute review” (Slip op. at 7), and then concluded “[s]ection 314(d) bars judicial review” (*id.* at 8). But BioDelivery should be allowed to identify the issues it wants to have judicially reviewed. And as explained above, the Court has full authority to review BioDelivery’s appeals on the merits. The dismissal further deprived BioDelivery of due process.

VI. AFTER DUE PROCESS ON REMAND, THE PTAB SHOULD CHANGE ITS PATENTABILITY DETERMINATION

The majority justified the dismissal of BioDelivery’s appeals before argument on the merits, in part, with its belief that “additional proceedings ... would have likely led to the same outcome.” Slip Op. at 8. But due process should change the outcome.

If allowed to argue the merits on remand, BioDelivery would demonstrate, inter alia, that the PTAB’s view of patentability depends on its misunderstanding of the state of the art as to film uniformity. The challenged patent erroneously asserts that prior art film “would *not likely* meet the stringent standards of [FDA] relating to the variation of active in dosage forms.” US Patent 8,765,167 at 2:12-

15 (emphasis added). Patent Owner argued that “[t]he films of the ‘167 Patent achieve a superior uniform distribution,” and identified the claimed uniformity as the reason not to proceed. Patent Owner Brief Regarding Remand, IPR2015-00165, Paper 83, at 2. The remand decisions found no reasonable expectation prior art film would satisfy the claimed uniformity. *See* IPR2015-00165-DOR at 23; *see also* IPR2015-00168-DOR at 9; IPR2015-00169-DOR at 36.

Nonetheless, petition evidence demonstrates that processes for achieving film uniformity were well known. The PTAB rejected that evidence as inconsistent with “the problem identified in the specification of the ‘167 patent.” IPR2015-00165-DOR at 20-23, 23. But no evidence supports the alleged uniformity problem. In other words, the PTAB rejected evidence in favor of an allegation that there was a uniformity problem.

Moreover, evidence proffered on remand proves that the allegedly “superior” film uniformity was known, and the FDA had approved film dosage units. *See* BioDelivery’s Responsive Briefing on Remand, IPR2015-00165, Paper 88, at 3 (proffering evidence). The PTAB chose not consider the proffered evidence on the state of the art as to film uniformity. *See* IPR2015-00165-DOR at 7; IPR2015-00169-DOR at 6; IPR2015-00168-DOR at 8 (reconsideration based on selected evidence).

In effect, at Patent Owner’s suggestion, but *without evidentiary support*, the Board tipped the scales in favor of patentability by presuming the patent solved a long felt, but unmet, firm “uniformity” need.² Considering the true state of the art on remand, the PTAB should find the challenged claims unpatentable.

VII. CONCLUSION

For the foregoing reasons, Petitioner/Appellant asks the full Court to grant rehearing of the motion to dismiss *en banc*, reverse the precedential Dismissal Order of the panel majority, and allow Petitioner/Appellant to be heard on the merits of its consolidated appeals.

Dated: September 30, 2019

Respectfully submitted,

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² The presumption is disturbing because there is no evidence the inventors had achieved the claimed uniformity.

CERTIFICATE OF COMPLIANCE

I certify that the foregoing Petition of the Appellant complies with the 3,900 word limit of Fed. R. App. P. 35(b)(2)(A), containing 3,897 words as determined by the word-count function of Microsoft Word, excluding the portions of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 35(c)(2).

I certify that this brief complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because the brief has been composed in a proportionally spaced typeface using Microsoft WORD in 14-point Times New Roman font.

Dated: September 30, 2019

Respectfully submitted,

/s/ Kia L. Freeman
Kia L. Freeman

ADDENDUM

**United States Court of Appeals
for the Federal Circuit**

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Appellant

v.

**AQUESTIVE THERAPEUTICS, INC., FKA
MONOSOL RX, LLC,**
Appellee

2019-1643, 2019-1644, 2019-1645

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

ON MOTION

KIA LYNN FREEMAN, McCarter & English, LLP, Boston,
MA, for appellant. Also represented by THOMAS F. FOLEY,
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San Francisco, CA; KATHERINE DOROTHY CAPPAERT, Wash-
ington, DC.

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Before NEWMAN, LOURIE, and REYNA, *Circuit Judges*.

Order for the court filed by *Circuit Judge* REYNA.

Opinion dissenting filed by *Circuit Judge* NEWMAN.

REYNA, *Circuit Judge*.

ORDER

Aquestive Therapeutics, Inc. moves to dismiss these appeals on the basis that our review is barred by 35 U.S.C. § 314(d). BioDelivery Sciences International, Inc. opposes the motion. Having considered the parties’ arguments, we grant the motion and dismiss these appeals.

BACKGROUND

In October 2014, BioDelivery filed three petitions for *inter partes* review (“IPR”) of U.S. Patent No. 8,765,167. The petitions contained a combined total of seventeen grounds. The petition in IPR2015-00165 included seven grounds, the petition in IPR2015-00168 included five grounds, and the petition in IPR2015-00169 included five grounds.

The Patent Trial and Appeal Board (“Board” or “PTAB”) instituted review on a single ground in each petition. For the fourteen other non-instituted grounds, the Board found that BioDelivery failed to establish a reasonable likelihood of prevailing on the merits. In the final written decisions, the Board sustained the patentability of all claims subject to the instituted challenges in each proceeding. BioDelivery appealed.

After oral argument in the appeals, the Supreme Court issued its decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). BioDelivery subsequently moved to remand the appeals based on SAS’s requirement that IPR proceedings must proceed “‘in accordance with’ or ‘in conformance to’ the petition,” *id.* at 1356 (quoting *Pursuant*, Oxford English Dictionary, <http://www.oed.com/view/Entry/155073>),

including “each claim challenged’ and ‘the grounds on which the challenge to each claim is based,” *id.* at 1355 (quoting 35 U.S.C. § 312(a)(3)).

We granted BioDelivery’s motion without deciding the merits of any of the appealed issues and vacated the Board’s final written decisions in the three IPR proceedings. *BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018) (“*Remand Order*”). Specifically, we ordered that “BioDelivery’s request for remand to implement the Court’s decision in *SAS* is granted in [the three appeals]” and “[t]he PTAB’s decisions in PTAB Nos. IPR2015-00165, IPR2015-00168, and IPR2015-00169, are vacated.” *Id.*

On remand, the Board requested briefing on whether it would be appropriate to vacate its prior institution decisions and deny the petitions in their entirety. *See BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol RX, LLC*, No. IPR2015-00165, Paper No. 91 (P.T.A.B. Feb. 7, 2019) (“PTAB Remand Dec. IPR2015-00165”), at 3; *BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol RX, LLC*, No. IPR2015-00168, Paper No. 88 (P.T.A.B. Feb. 7, 2019) (“PTAB Remand Dec. IPR2015-00168”), at 3; *BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol RX, LLC*, No. IPR2015-00169, Paper No. 89 (P.T.A.B. Feb. 7, 2019) (“PTAB Remand Dec. IPR 2015-00169”), at 3. After considering the parties’ arguments and whether petitioner had shown a reasonable likelihood of prevailing on all grounds, including those which were not previously instituted, the Board modified the institution decisions, denied the petitions, and terminated the proceedings. *E.g.*, PTAB Remand Dec. IPR2015-00165 at 3.

The Board emphasized its discretion to institute IPR under 35 U.S.C. § 314(a) even upon a showing of a reasonable likelihood of prevailing on at least one challenged claim. *Id.* at 5 (citing *SAS*, 128 S. Ct. at 1356). The Board

also emphasized its statutory directive to prescribe regulations for conducting IPR and the Director's obligation to "consider the effect of any such regulation on . . . the efficient administration of the Office." *Id.* (quoting 35 U.S.C. § 316(b)); *see also* 37 C.F.R. § 42.1(b) ("This part shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding.").

The Board considered the merits of the previously non-instituted grounds and found that BioDelivery had not "establish[ed] a reasonable likelihood of success in relation to those claims and grounds." *Id.* at 7. "Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, [the Board found] that instituting trial as to those grounds at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding." *Id.*

Although BioDelivery argued that the finality requirement of § 314(d) prohibited the Board from reconsidering its decisions to institute, the Board rejected that argument and noted that it has previously reconsidered institution decisions and terminated IPR proceedings without issuing a final decision. *Id.* at 8–10 (citing *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016); *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313 (Fed. Cir. 2015)). In applying SAS and making the "binary choice" to either institute review or not, the Board reevaluated the petitions and declined to institute. *Id.* at 10 (quoting *SAS*, 138 S. Ct. at 1355).

BioDelivery then filed these appeals of the Board's decisions on remand.

DISCUSSION

Section 314(a) of the Leahy-Smith America Invents Act provides that

[t]he Director¹ may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that 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) (footnote added). Subsection (a) identifies a threshold requirement that must be met before the Director is even authorized to institute review, and then “grants the Director discretion not to institute even when the threshold is met.” *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018) (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)). In other words, the Director is limited in his power to institute review but has discretion to not institute review even when the threshold showing is met. *See Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (“While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons such as administrative efficiency”), *cert. denied*, 139 S. Ct. 1547 (2019).

In *SAS*, the Supreme Court held that the Patent Office exceeded its statutory authority by limiting its review to fewer than all of the claims challenged in the IPR petitions. *SAS*, 138 S. Ct. at 1359–60. The Court said that § 314 “indicates a binary choice—either institute review or don’t.” *Id.* at 1355.

In *PGS*, we recognized the Court’s holding “that the IPR statute does not permit a partial institution on an IPR

¹ The Director has delegated the authority on whether to institute review to the Board. 37 C.F.R. § 42.4(a).

petition.” *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1359 (Fed. Cir. 2018). We stated that under SAS, the statute “require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.” *Id.* at 1360. In our *Remand Order* in this case, we also recognized that “the statute does not permit a partial institution leading to a partial final written decision.” *Remand Order*, 898 F.3d at 1208 (quoting *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1371 n.1 (Fed. Cir. 2018)).

Section 314(d) plainly states that the Patent Office’s decision whether to institute IPR is not appealable. *See Cuozzo*, 136 S. Ct. at 2139. As the Board recognized, we have previously held that under § 314(d), “[t]he Board’s vacatur of its institution decisions and termination of the proceedings constitute decisions whether to institute inter partes review and are therefore ‘final and nonappealable.’” *Medtronic*, 839 F.3d at 1383 (quoting 35 U.S.C. § 314(d)); *see also GTNX*, 789 F.3d at 1313.

Although BioDelivery argues to the contrary, there is no requirement that once instituted, IPRs must proceed through final written decisions. Indeed, § 318(a) on its face provides that a “proceeding can be ‘dismissed’ after it is instituted.” *Medtronic*, 839 F.3d at 1385. We have also recognized 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 *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). Nothing “clearly deprives” the Board from exercising that inherent, “default authority” here. *Id.* at 1385–86 (quoting *GTNX*, 789 F.3d at 1313).

Despite the “strong presumption in favor of judicial review” when interpreting statutes, Congress clearly intended to bar review of institution decisions in at least some circumstances by passing the “No Appeal”

provision—§ 314(d). “[W]here a patent holder merely challenges the Patent Office’s ‘determin[ation] that 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,’ . . . § 314(d) bars judicial review.” *Cuozzo*, 136 S. Ct. at 2142.

We have such a case here; BioDelivery’s appeals merely challenge the Board’s determination *not* to institute review, something the Board has discretion to do even upon a showing that there is a “reasonable likelihood of success with respect to at least 1 claim challenged” in the petition. As in *Medtronic*, we would be “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—statutory language that is not limited to an *initial* determination to the exclusion of a determination on reconsideration.” 839 F.3d at 1386 (quoting *GTNX*, 789 F.3d at 1312). “[S]uch a decision is ‘final and nonappealable.’” *Id.* (quoting *GTNX*, 789 F.3d at 1312).

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.

Alternatively, the Board could have implemented *SAS* by revisiting its institution decisions and deciding to institute review on all challenges raised in the petitions. This course of action would have required the Board to conduct full trial proceedings on all challenges, including supplemental briefing, additional discovery, and further oral argument. See *Guidance on the Impact of SAS on AIA Trial Proceedings*, U.S. Patent & Trademark Office (Apr. 26,

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2018), <https://www.uspto.gov/patentsapplication-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>. These additional proceedings would have related to the fourteen additional challenges that the Board determined did not meet the threshold standard for institution in the first place and would have likely led to the same outcome.

Undertaking such proceedings would contravene the Director's statutory charge to consider the efficiency of the Patent Office in conducting IPR proceedings. *See* 35 U.S.C. § 316(b). It would also contravene the Director's own regulations promulgated pursuant to that statutory charge, which require the Patent Office to "secure the just, speedy, and inexpensive resolution of every proceeding." 37 C.F.R. § 42.1(b).

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 petitions 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. Section 314(d) bars judicial review of both aspects of the Board's decisions. *Cuozzo*, 136 S. Ct. at 2142.

Accordingly,

IT IS ORDERED THAT:

The above-captioned appeals are dismissed.

FOR THE COURT

August 29, 2019
Date

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

BIODELIVERY SCIS. INT'L v. AQUESTIVE THERAPEUTICS, INC. 9

ISSUED AS A MANDATE: August 29, 2019

**United States Court of Appeals
for the Federal Circuit**

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Appellant

v.

**AQUESTIVE THERAPEUTICS, INC., FKA
MONOSOL RX, LLC,**
Appellee

2019-1643, 2019-1644, 2019-1645

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

NEWMAN, *Circuit Judge*, dissenting.

The Patent Trial and Appeal Board, on remand from the Federal Circuit, rejected this Court's remand instruction to implement the Supreme Court's holding in *SAS Institute*. The Board's action departs from principles of appellate review, and negates the agency's obligations under the America Invents Act. From my colleagues' endorsement of these irregular positions, I respectfully dissent.

The Federal Circuit's Remand Order

Three petitions for inter partes review ("IPR") were filed by BioDelivery. The PTAB granted the petitions on selected claims and a single ground for each petition, as

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practice then permitted. Trial was held with witnesses, testimony, briefing and argument, followed by three final written decisions, all sustaining validity of the claims examined. These decisions were duly appealed by BioDelivery, briefed and argued in the Federal Circuit, and awaited our decision.

Meanwhile, the Supreme Court decided *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). The Court held that the IPR statute, 35 U.S.C. § 318(a), requires that if an IPR petition is granted and review is instituted, the PTAB must decide all the claims and grounds that were raised in the petition. *Id.* at 1354. Since here the PTAB had not met these requirements, we remanded 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 PTAB held that it would be inefficient and expensive to implement the Supreme Court’s decision. *See BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, No. IPR2015-00165, Paper No. 91 (P.T.A.B. Feb. 7, 2019), at 28 (“[W]e find that instituting trial as to those grounds at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding.”); *see also BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, No. IPR2015-00168, Paper No. 88 (P.T.A.B. Feb. 7, 2019), at 8; *BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, No. IPR2015-00169, Paper No. 89 (P.T.A.B. Feb. 7, 2019), at 37. Instead, the PTAB withdrew all of its actions as to these three IPRs.

My colleagues hold that since the PTO is not required to accept any petition for IPR, the PTO can now withdraw its initial acceptance and all ensuing proceedings as if they never occurred, and negate our Remand Order. However, the question is not whether the PTO could have initially declined to institute these reviews; the question is whether

BIODELIVERY SCIS. INT'L v. AQUESTIVE THERAPEUTICS, INC. 3

the PTO must comply with this court's Remand Order and implement the ruling of the Supreme Court. That is, must the PTO conform to standard administrative practice whereby the agency must comply with the remand instruction of the reviewing court.

Appellate courts have statutory authority to remand for further proceedings:

The Supreme Court or any other court of appellate jurisdiction may . . . remand the cause and direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as may be just under the circumstances.

28 U.S.C. § 2106. The obligation to comply with a remand order is beyond debate, whether remand is to a lower court or an administrative agency. *See, e.g., City of Cleveland v. Fed. Power Comm'n*, 561 F.2d 344, 346 (D.C. Cir. 1977) (“The decision of a federal appellate court establishes the law binding further action in the litigation by another body subject to its authority. . . . These principles, so familiar in operation within the hierarchy of judicial benches, indulge no exception for reviews of administrative agencies.”); *see also In re Sanford Fork & Tool Co.*, 160 U.S. 247, 255 (1895) (“When a case has been once decided by this court on appeal, and remanded to the circuit court, whatever was before this court, and disposed of by its decree, is considered as finally settled. The circuit court is bound by the decree as the law of the case, and must carry it into execution according to the mandate. That court cannot vary it, or examine it for any other purpose than execution. . . .”).

Precedent illustrates this rule as followed by agencies and courts, without quibble. *See Braniff Airways, Inc. v. C. A. B.*, 379 F.2d 453, 468 n.11 (D.C. Cir. 1967) (“We have frequently remanded agency cases with specific directions, and we have no reservations about our statutory power to do so.”) (citations omitted); *Mefford v. Gardner*, 383 F.2d 748, 758 (6th Cir. 1967) (“[O]n the remand of a case after

appeal, it is the duty of the lower court, or the agency from which appeal is taken, to comply with the mandate of the court”); *see also Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, Paper No. 87 (P.T.A.B. Feb. 11, 2019), at 20 (“As an initial matter, we recognize that we are bound by the mandate on matters that the mandate addressed.”).

For PTO tribunals, 35 U.S.C. § 144 assigns review obligations to the Federal Circuit:

The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office. Upon its determination the court shall issue to the Director its mandate and opinion, which shall be entered of record in the Patent and Trademark Office and shall govern the further proceedings in the case.

Here, the PTAB decisions were duly appealed to the Federal Circuit, where they were briefed and argued. When the Supreme Court decided *SAS Institute*, we recognized the applicability and because the record was not complete for the issues on appeal, we remanded to the PTAB with instructions “to implement the Court’s decision is *SAS*.” Remand Order, 898 F.3d at 1210.

Nonetheless, the PTAB declined to execute our Remand Order. Instead, the PTAB discarded these three completed IPR cases as if they had never occurred. However, “actions on remand should not be inconsistent with either the letter or the spirit of the mandate.” *Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed. Cir. 1997); *see also Quern v. Jordan*, 440 U.S. 332, 347 n.18 (1979) (“[W]e remanded the matter . . . , and we hold today that the award . . . is not inconsistent with either the spirit or express terms of our decision”); *Banks v. United States*, 721 F. App’x 928, 933 (Fed. Cir. 2017) (“After our mandate issues, the mandate rule forecloses reconsideration of

issues implicitly or explicitly decided on appeal . . . [B]oth the letter and the spirit of the court's mandate must be considered."); *Best Key Textiles Co. v. United States*, 660 F. App'x 905, 906 (Fed. Cir. 2016) ("When a trial court interprets a mandate from this court, both the letter and the spirit of the mandate must be considered.") (internal quotation marks omitted); *SUFI Network Servs., Inc. v. United States*, 817 F.3d 773, 779 (Fed. Cir. 2016) ("[I]n interpreting this court's mandate, both the letter and the spirit of the mandate must be considered."); *Bankers Trust Co. v. Bethlehem Steel Corp.*, 761 F.2d 943, 949 (3d Cir. 1985) ("A trial court must implement both the letter and spirit of the mandate, taking into account the appellate court's opinion and the circumstances it embraces.").

The PTAB's action is not consistent with the "letter or spirit of the mandate," which ordered further proceedings in conformity to the Court's ruling in *SAS*. This Remand Order requires compliance, not avoidance at the agency's option. However, my colleagues endorse the PTAB's action, reasoning that since it was within the PTAB's authority to decline to institute these IPR petitions, that action and all ensuing proceedings can be retroactively cancelled, at the PTAB's unreviewable choice.

The PTO indeed had discretion to decline to institute these IPRs. However, here the PTO did institute the IPRs, and conducted full trials and issued final written decisions on the aspects it considered. Although my colleagues state that "there is no requirement that once instituted, IPRs must proceed through final written decisions," Maj. Op. at 6, here the three IPRs did proceed through final written decisions. The Court has ruled that these decisions must include all the claims and grounds raised by the petition. Our Remand Order and instruction was to implement the Supreme Court's holding, which was "that *SAS* is entitled to a final written decision addressing all of the claims it has challenged." *SAS*, 138 S. Ct. at 1359–60. BioDelivery is entitled to such decision.

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Incidentally, I take note that my colleagues state that “[t]he Board considered the merits of the previously non-instituted grounds and found that BioDelivery had not ‘establish[ed] a reasonable likelihood of success in relation to those claims and grounds.’” Maj. Op. at 4. However, the Board presented no final written decision as to all the claims and grounds in the petitions.

The PTO’s action in response to our Remand Order fails not only the Supreme Court’s requirement, but the PTO’s assignment under the America Invents Act to resolve certain validity issues by agency IPR proceeding. From my colleagues’ endorsement of the agency’s action, I respectfully dissent.

CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2019, I electronically filed the foregoing with the Court's CM/ECF filing system, which constitutes service, pursuant to Fed. R. App. P. 25(c)(2) and Fed. Cir. R. 25(e).

Respectfully submitted,

/s/ Kia L. Freeman