No. 19-

IN THE

Supreme Court of the United States

BIODELIVERY SCIENCES INTERNATIONAL, INC.,

Petitioner,

v.

AQUESTIVE THERAPEUTICS, INC.,
F/K/A MONOSOL RX, LLC

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. The Federal Circuit vacated three inadequate final written decisions and remanded the inter partes reviews (IPRs) with the order to implement this Court's decision in *SAS*. On its own initiative on remand, the Patent Office instead terminated the instituted IPRs. The Federal Circuit dismissed the appeal of the termination decisions, holding it lacked authority to review those decisions.

Does the Judiciary have authority to review a Patent Office decision refusing to implement its mandate and this Court's precedent?

2. The Patent Office terminated three IPRs that had already been instituted. The Patent Office has no discretionary authority to terminate an instituted IPR—as long as the petitioner remains involved. But the Patent Office mislabeled the termination decisions as nonappealable decisions whether to institute the IPRs.

May a petitioner appeal a decision terminating an instituted IPR, despite the decision being mislabeled as a nonappealable decision?

PARTIES TO THE PROCEEDING

All parties to the proceedings are listed in the caption.

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.

RULE 14.1(b)(iii) DIRECTLY RELATED PROCEEDINGS

The proceedings in the United States Patent and Trademark Office and United States Court of Appeals for the Federal Circuit identified below are directly related to the above captioned case in this Court.

BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC, Federal Circuit Consolidated Case Nos. 2017-1265, 2017-1266, 2017-1268. The Federal Circuit entered its Remand Order, reported at 898 F.3d 1205, on July 31, 2018.

BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC, United States Patent and Trademark Office, Patent Trial and Appeal Board Case IPR2015-00165. The PTAB entered its Decision on Remand, reported at 2019 WL 494351, on February 7, 2019.

BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC, United States Patent and Trademark Office, Patent Trial and Appeal Board Case IPR2015-00168. The PTAB entered its Decision on Remand, reported at 2019 WL 494352, on February 7, 2019.

BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC, United States Patent and Trademark Office, Patent Trial and Appeal Board Case IPR2015-00169. The PTAB entered its Decision on Remand, reported at 2019 WL 494355, on February 7, 2019.

BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc. f/k/a MonoSol Rx, LLC, Federal Circuit Consolidated Case Nos. 2019-1643, 2019-1644, 2019-1645. The Federal Circuit entered its Dismissal Order, reported at 935 F.3d 1362, on August 29, 2019. The Federal Circuit entered its Order denying rehearing, reported at 946 F.3d 1382, on January 13, 2020.

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Petitioner BioDelivery Sciences International, Inc. respectfully requests a writ of certiorari to review the judgment by the United States Court of Appeals for the Federal Circuit dismissing Petitioner's consolidated appeals of the Decisions on Remand by the Patent Trial and Appeal Board.

OPINIONS BELOW

The order by the United States Court of Appeals for the Federal Circuit dismissing BioDelivery's consolidated appeals of the Decisions on Remand was reported at 935 F.3d 1362 (August 29, 2019) and is reprinted in the Appendix to the Petition ("App."), *infra*, at 1a-16a.

The Patent Trial and Appeal Board's three Decisions on Remand, all issued on February 19, 2019, are reported at 2019 WL 494351, 2019 WL 494352, and 2019 WL 494355 and reprinted in the Appendix, *infra*, at 17a-48a, 49a-83a, and 84a-124a, respectively.

The order by the Federal Circuit granting BioDelivery's motion, vacating the inadequate final written decisions, and remanding the proceedings to the Board was reported at 898 F.3d 1205 (July 31, 2018) and is reprinted in the Appendix, *infra*, at 136a-145a.

The order denying rehearing of the dismissal of the consolidated appeals of the Decisions on Remand was reported at 946 F.3d 1382 (January 13, 2020) and is reprinted in the Appendix, *infra*, at 125a-135a.

JURISDICTION

The order dismissing the consolidated appeals below was entered on August 29, 2019. A timely request for rehearing was denied on January 13, 2020. In its March 19, 2020 Order in light of COVID-19, this Court extended the deadline to file a petition for a writ of certiorari to 150 days from the order denying rehearing. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS

35 U.S.C. § 144:

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.

35 U.S.C. § 314(d):

No Appeal.--The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

35 U.S.C. § 316(c):

Patent Trial and Appeal Board.--The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

35 U.S.C. § 317(a):

In General.--An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner's institution of that inter partes review. If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

35 U.S.C. § 318(a):

Final Written Decision.--If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

INTRODUCTION AND STATEMENT OF THE CASE

This case arises from the institution of three inter partes reviews ("IPRs"). The IPRs were instituted in response to BioDelivery's petitions, each challenging different subsets of claims of U.S. Patent No. 8,765,167[1]

1. The technology claimed in the '167 patent is not material to this petition.

on multiple grounds. The Patent and Trademark Office's ("PTO's") Patent Trial and Appeal Board ("PTAB") excluded petition challenges from the scope of each of the three instituted IPRs, excluded challenged claims from one of the three instituted IPRs, and then issued "final written decisions" that failed to address all of the petition challenges. Each of the three "final written decisions" found that BioDelivery had failed to meet its burden on the challenges within the scope of the instituted review. BioDelivery appealed the "final written decisions," and the Office Director intervened to modify the reasoning set forth in those decisions.

While BioDelivery's consolidated appeals were pending, this Court decided *SAS Institute v. Iancu*. In *SAS*, the Court considered the question: "When the Patent Office initiates an inter partes review, must it resolve *all* of the claims in the case or may it choose to limit its review to only *some* of them?" 138 S. Ct. 1348, 1352-53 (2018) (emphasis original). "SAS argued that 35 U.S.C. § 318(a) required the Board to decide the patentability of every claim SAS challenged in its petition, not just some." *Id*. at 1354. The Court explained: "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 of the claims it raises, not just those the decisionmaker might wish to address." *Id*. at 1355.

The Court rejected "the Director's view [that] he retains discretion to decide which claims make it into an inter partes review and which don't." *Id*. It explained that, under 35 U.S.C. § 314(a), "a reasonable prospect of success on a single claim justifies review of all." *Id*. at 1356. The Court rejected both parties' policy arguments related

to efficiency. It explained, "Congress's prescribed policy here is clear: the petitioner in an inter partes review is entitled to a decision on all the claims it has challenged." *Id.* at 1358.

The Court also rejected the Director's argument that § 314(d) and *Cuozzo* foreclosed judicial review of any legal question bearing on the institution of inter partes review. It explained that "nothing in § 314(d) or *Cuozzo* withdraws our power to ensure that an inter partes review proceeds in accordance with the law's demands." *Id.* at 1359. "Because everything in the statute before us confirms that *SAS is entitled to a final written decision* addressing all of the claims it has challenged and nothing suggests we lack the power to say so, the judgment of the Federal Circuit is reversed and the case is remanded for further proceedings consistent with this opinion." *Id.* at 1359-60 (emphasis added). In sum, *SAS* held that a petitioner who properly protested that an existing final written decision failed to comply with § 318(a) is entitled to a complete final written decision.

Shortly thereafter, in *PGS Geophysical AS v. Iancu,* the Federal Circuit applied the reasoning in *SAS* and found that 35 U.S.C. § 318(a) further requires a final written decision to address every patentability challenge in the underlying petition. *See* 891 F.3d 1354, 1359-60 (Fed. Cir. 2018). Nonetheless, the Federal Circuit held that it need not and would not enforce that statutory requirement on its own initiative. *See Id.* at 1362. In view of *SAS* and *PGS*, all of the final written decisions at issue in BioDelivery's consolidated appeals failed to comply with § 318(a).

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 Therapeutics, Inc. et al.*, CAFC Appeal Nos. 17-1265, -1266, -1268, Dkt. 91, (June 19, 2018), App. 156a. Aquestive and the Intervenor opposed only on the basis that BioDelivery, by not asserting them sooner, had waived its rights to final written decisions compliant with section 318(a). In granting BioDelivery's motion, the Federal Circuit recognized "[t]he inadequacy of the three PTAB decisions, as established by *SAS*." *BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc. et al.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018) (decision hereinafter "Remand Order"), App. 144a. "We agree that *SAS* requires institution on all challenged claims and all challenged grounds." *Id.*, App. 143a. Accordingly, the Federal Circuit vacated the inadequate final written decisions and granted "BioDelivery's request for remand to implement the Court's decision in *SAS*." *Id.*, App. 145a.

On remand, the PTAB did not issue final written decisions. The PTAB did not allow any argument or evidence on the merits of any of BioDelivery's excluded petition challenges. The PTAB only invited and allowed briefing on whether it would be appropriate to vacate its prior institution decisions and deny the petitions in their entirety. In its briefing, BioDelivery explained that vacatur of the decisions to institute would be inappropriate. In view of the briefing, the PTAB did not vacate its prior decisions to institute. Instead, purporting to modify its prior decisions to institute the IPRs, the PTAB issued Decisions on Remand terminating the IPRs. In doing so, the PTAB claimed to exercise an alleged inherent,

discretionary authority to reverse a prior decision to institute at any time.

BioDelivery filed notices of appeal for each of the three Decisions on Remand. Shortly thereafter, in each of the three appeals, Patent Owner filed identical motions to dismiss for lack of jurisdiction. In its opposition, BioDelivery invoked the jurisdiction of the Federal Circuit under 28 U.S.C. § 1295, 35 U.S.C. § 144, and 5 U.S.C. §§ 701-706.

In its motion to dismiss, Patent Owner argued "review is barred by 35 U.S.C. § 314(d)." *BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 935 F.3d 1362, 1363 (Fed. Cir. 2019) (decision hereinafter "Dismissal Order"), App. 2a. After the consolidation of the appeals, a panel majority noted that the Federal Circuit had "previously held that under § 314(d), the Board's vacatur of its institution decisions and termination of the proceedings constitute decisions whether to institute inter partes review and are … final and nonappealable." Dismissal Order, App. 7a (internal quotations and citations omitted). The panel majority noted that the Federal Circuit had "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.* (internal quotations and citations omitted). The panel majority found "[n]othing clearly deprives the Board from exercising that inherent default authority here." *Id.* (internal quotations and citations omitted).

Without having allowed any briefing on the merits, the panel majority also concluded that "BioDelivery's

appeals merely challenge the Board's determination not to institute review." *Id.*, App. 8a. Accordingly, a divided panel dismissed BioDelivery's appeals, holding that "[s]ection 314(d) bars judicial review …." *Id.*, App. 9a citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016).

Judge Newman dissented from the reasoning and holding of the panel majority in the Dismissal Order. According to the dissent, *SAS* "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 the grounds that were raised in the petition." Dismissal Order, App. 11a (Newman, J., dissenting). "Since here the PTAB had not met those requirements, we remanded with instructions to 'implement the Court's decision in *SAS*.'" *Id.* According to the dissent, "the PTAB held that it would be inefficient and expensive to implement the Supreme Court's [*SAS*] decision." *Id.*, App. 12a. To avoid that burden, "the PTAB withdrew all of its actions as to these three IPRs." *Id.* According to the dissent, "[t]he PTAB's action is not consistent with the 'letter or spirit of the mandate,' which ordered further proceedings in conformity with the Court's ruling in *SAS*." *Id.*, App. 15a. In other words, "the PTAB declined to execute our Remand Order." *Id.*, App. 14a. The dissent recognized that the majority held that the PTO can now "negate our Remand Order." *Id.*, App. 12a. But the dissent opined that the "Remand Order requires compliance, not avoidance at the agency's option." *Id.*, App. 15a.

The Federal Circuit later denied rehearing of the Dismissal Order. *BioDelivery Scis. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 946 F.3d 1382, 136 (Fed. Cir. 2020) (decision hereinafter "Denial Order"), App.

125. Judge Newman also dissented from the Denial Order—emphasizing in her dissent "the significance of the balance of agency and judicial authority, and the rules of procedural law in the administrative state." App., 127a.

Two cases based on the allegation that BioDelivery infringes the challenged '167 patent are pending. The first case was brought by both Reckitt Benckiser Pharmaceuticals, Inc. and Aquestive whereas the second case was brought by Aquestive alone.

REASONS FOR GRANTING THE PETITION

Invoking a nonexistent "inherent" authority to disregard judicial orders and this Court's precedent, the Patent Trial and Appeal Board ("PTAB") refused to reach complete final written decisions in three instituted inter partes reviews ("IPRs"), even after receiving a mandate from the Federal Circuit to implement this Court's decision in *SAS*. The PTAB instead terminated the instituted IPRs on the grounds that continuing the IPRs as required to reach complete final written decisions—that is, complying with the mandate and implementing *SAS*—would be too much work. The PTAB characterized these terminations as decisions "whether to institute" under 35 U.S.C. § 314(d), in an apparent effort to avoid judicial review. And in a dangerous, precedential dismissal of the appeal, the Federal Circuit not only endorsed the nonexistent PTAB authority but also validated the effectivity of mislabeling a decision terminating an instituted IPR in order to prevent appeal. In doing so, the Federal Circuit abdicated its responsibility to rein in the PTAB when it, as here, exceeds its statutory authority. Allowed to stand, the Federal Circuit's decision below will invite the PTAB

to do as it pleases in terminating any instituted IPR and to make any IPR-ending decision nonappealable, simply by calling it a "decision whether to institute."

This petition presents a fundamental question of the limits on the PTAB's ability to flout judicial authority, and goes far beyond the mere application of *SAS*. It also presents the question of whether a decision validating a nonexistent PTAB authority—authority both contrary to the statutory scheme and used to avoid judicial review—can be allowed to stand.

I. THE DECISION BELOW, IF ALLOWED TO STAND, WOULD NEGATE FUTURE JUDICIAL AUTHORITY OVER THE PATENT OFFICE

The Decisions on Remand ("DORs") violated the Federal Circuit's remand order "to implement th[is] Court's decision in *SAS*." In *SAS*, this Court vacated a final written decision and remanded the IPR for further proceedings consistent with its finding that the petitioner "is entitled to a [complete] final written decision under 35 U.S.C. §318(a)."

Express statutory requirements of the America Invents Act ("AIA") and of the Administrative Procedures Act ("APA") and long-standing principles of agency jurisprudence require the Patent and Trademark Office ("Patent Office" or "PTO") to comply with the Federal Circuit's remand order. The PTO has no authority to refuse to comply with this Court's holding and the Federal Circuit's remand order. Nonetheless, the PTO invoked a nonexistent inherent discretionary authority to disregard the Judiciary. Rather than work toward the final written

decisions, to which petitioner was entitled on remand, the PTO terminated the instituted IPRs. The Federal Circuit's error—in finding that the PTO had inherent discretionary authority not to execute the remand order—is dangerous. The Federal Circuit's validation of the PTO's alleged inherent discretionary authority on remand nullifies the court's own mandate and judicial authority as to instituted IPRs. The Federal Circuit's abdication of its authority and responsibility should not be allowed to stand.

A. PTO Adherence to the Federal Circuit's Mandate is Not Optional

The Federal Circuit's mandate and opinion governs the PTO on remand. Both Congress (via statute) and the Judiciary (by precedent) require the PTO to follow the Federal Circuit's mandate. The PTO has no discretion to discard the Federal Circuit's mandate.

The APA provides appellate courts authority to remand an action to an agency and "require such further proceedings to be had as may be just." 28 U.S.C. § 2106. The AIA gives the Federal Circuit exclusive authority over an appeal from a PTAB decision under title 35. 28 U.S.C. § 1295(a)(4)(A). The AIA expressly provides that the Federal Circuit's "mandate and opinion … **shall** govern further proceedings in the case." 35 U.S.C. § 144 (emphasis added). "The word 'shall' generally imposes a nondiscretionary duty." *SAS*, 138 S. Ct. at 1354 (citing *Lexecon Inc. v. Millberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)). The PTAB's statutory obligation to follow the Federal Circuit's mandate is impervious to the PTAB's discretion.

Federal courts have long ensured that agencies conform to their statutory obligations by remanding insufficient decisions for further proceedings. *See, e.g., Ford Motor Co. v. N.L.R.B.*, 305 U.S. 364, 373 (1939) ("It is familiar appellate practice to remand causes for further proceedings."). "[T]he decision of a federal appellate court establishes the law binding further action in the litigation by another body subject to its authority." *City of Cleveland, Ohio v. Fed. Power Comm'n*, 561 F.2d 344, 346 (D.C. Cir. 1977).

Once the federal court issues a remand order, the administration agency has a "duty ... to comply with the mandate issued by a reviewing court." *In re Wella A.G.*, 858 F.2d 725, 728 (Fed. Cir. 1988); *see also Briggs v. Pennsylvania R.R.*, 334 U.S. 304, 306 (1948). "Judgments, within the powers vested in courts by the Judiciary Article of the Constitution, may not lawfully be revised, overturned or refused faith and credit by another Department of Government." *Chicago & S. Air Lines v. Waterman S. S. Corp.*, 333 U.S. 103, 113 (1948). "[A]n inferior court has no power or authority to deviate from the mandate issued by an appellate court." *Briggs,* 334 U.S. at 306. "[W]here an administrative agency has been ordered to reconsider or explain an earlier decision on remand, as is the case here, the agency has an 'affirmative duty to respond to the specific issues remanded' by the Court." *Oceana, Inc. v. Ross*, 321 F. Supp. 3d 128, 136 (D.D.C. 2018); *see also In re Wella*, 858 F.2d at 726 (TTAB must "comply with the mandate issued by" the Federal Circuit); *Scott v. Mason Coal Co.*, 289 F.3d 263, 267 (4th Cir. 2002) (agency must comply with "both the letter and the spirit of the ... mandate"). Accordingly, as part of an administrative agency, the PTAB has no discretion to disregard a valid mandate of the Federal Circuit.

B. The PTO Disregarded the Mandate to Implement *SAS*

1. Implementing *SAS* Requires the PTO to Issue Complete Final Written Decisions

While Petitioner BioDelivery's appeal of three final written decisions was pending, the judiciary clarified the rights of an IPR petitioner under 35 U.S.C. § 318(a). First, this Court issued its decision in *SAS Institute, Inc. v. Iancu*. In *SAS*, the Court considered the question: "When the Patent Office initiates an inter partes review, must it resolve *all* of the claims in the case or may it choose to limit its review to only *some* of them?" *SAS*, 138 S. Ct. 1348, 1352-53 (2018) (emphasis original). The Court found the PTO must resolve all of the claims in the IPR. *Id.*

The Court explained: "[m]uch as in the civil litigation system it mimics, in an [IPR] the petitioner is master of its complaint and normally entitled to judgment on all of the claims it raises, not just those the decisionmaker might wish to address." *SAS*, 138 S. Ct. at 1355. "Congress's prescribed policy here is clear: the petitioner in an [IPR] is entitled to a decision on all the claims it has challenged." *Id.* at 1358. In *SAS*, the Court found that "nothing in § 314(d) or *Cuozzo* withdraws our power to ensure than an [IPR] proceeds in accordance with the law's demands." *Id.* at 1359.

Ultimately, the Court held: "Because everything in the statute before us confirms that SAS is **entitled to a final written decisio**n addressing all of the claims it has challenged and nothing suggests we lack the power to say so, the judgment of the Federal Circuit is reversed and the case is remanded for further proceedings consistent

with this opinion." *Id.* at 1359-60 (emphasis added). In short, *SAS* held that a petitioner in an instituted IPR is entitled to a **complete** final written decision. *Id.* at 1359; *see also Thryv, Inc. v. Click-to-Call Techns., LP*, 140 S. Ct. 1367, 1376 (2020) ("*SAS Institute* first held that once the agency institutes an [IPR], it must 'resolve **all** of the claims in the case.'") (emphasis original); Dismissal Order, App. 11a ("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.") (Newman, J., dissenting).

Shortly after *SAS*, the Federal Circuit issued its decision in *PGS Geophysical AS v. Iancu*. In *PGS*, the Federal Circuit found that "[e]qual treatment of claims and grounds for institution purposes has pervasive support in *SAS*." *PGS*, 891 F.3d 1354, 1360 (Fed. Cir. 2018). "Although 35 U.S.C. § 318(a), the primary statutory ground of decision, speaks only of deciding all challenged and added 'claim[s],' the Supreme Court spoke more broadly when considering other aspects of the statutory regime, and it did so repeatedly." *PGS*, 891 F.3d at 1360. In light of *SAS*, the Federal Circuit considered "[w]hether [it had] jurisdiction to address [the patent owner's] appeals" of final written decisions that did not address all of the petition challenges. *Id.* at 1359. The Federal Circuit found jurisdiction under the APA because the appealed decisions "'terminated the IPR proceeding' as to **all** claims and all grounds." *Id.* at 1360-62 (emphasis added).

2. Previously, The Federal Circuit Ordered the PTO to Implement this Court's Decision in *SAS*

In view of *SAS* and *PGS*, each of the final written decisions in BioDelivery's (prior) pending consolidated appeal were deficient under § 318(a). The PTAB instituted three IPRs, but improperly excluded some petition challenges from the scope of each review. Remand Order, App. 136a. Because none of them addressed all of the challenges in the underlying petition, as required by *SAS* and *PGS*, the three final written decisions at issue in BioDelivery's appeal failed to comply with § 318(a). Accordingly, BioDelivery moved to have the inadequate final written decisions vacated and the IPRs remanded, expressly "request[ing] a final written decision that satisfied the requirements of 35 U.S.C. § 318(a) as interpreted by SAS and PGS." App. 160a.

The Federal Circuit agreed with BioDelivery, recognizing that the three PTAB decisions were "inadequa[te]" under *SAS*. Remand Order, App. 144a. The Federal Circuit also recognized the Court's holding in *SAS* that "if the Director institutes [IPR] proceedings, the PTAB **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,' …." Remand Order, App. 138a-139a (internal citations omitted) (emphasis added). And "[it] agree[d] that *SAS* **requires institution** on all challenged claims and all challenged grounds." Remand Order, App. 143a (emphasis added). Accordingly, the Federal Circuit vacated the inadequate final written decisions at issue in BioDelivery's appeal and granted "BioDelivery's request

for remand to implement the Court's decision in *SAS*." Remand Order, App. 145a; *see also* Dismissal Order, App. 3a ("We … vacated the Board's final written decisions in the three IPR proceedings.").

There is no mystery what "implement[ing] the Court's decision in *SAS*" requires. In similar remand orders in other cases, the Federal Circuit has explained that implementation of *SAS* on remand requires the PTAB to address all petition challenges in a final written decision. *See, e.g.*, *Adidas AG v. Nike, Inc.*, 894 F.3d 1256, 1258 (Fed. Cir. 2018) (granting remand in view of *SAS* and ordering "[t]he Board … to promptly issue a **final written decision** as to all grounds raised in Adidas's petitions.") (emphasis added); *Broad Ocean Techs., LLC v. Nidec Motor Corp.*, 727 Fed. Appx. 686, 687 (Fed. Cir. 2018) (remanding in view of *SAS* for "issuance of a Final Written Decision" addressing claims excluded from the review); *Baker Hughes Oilfield v. Smith Int'l, Inc.*, Nos. 2018-1754, -1755, 2018 WL 4087705, *3 (Fed. Cir. 2018) (remanding in view of *SAS* "to promptly conduct further proceedings and issue final written decisions."); *Palo Alto Networks, Inc. v. Finjan, Inc.*, 752 Fed. Appx. 1017, 1021 (Fed. Cir. 2018) ("Because the -00151 IPR FWD addresses fewer than all claims challenged in the Palo Alto's petition to institute …, we vacate and remand to allow the Board to issue a Final Written Decision consistent with *SAS*."); *Alere, Inc. v. Rembrandt Diagnostics, LP*, 791 Fed. Appx. 173, 178 (Fed. Cir. 2019) ("Under *SAS*, … the Board erred by instituting review on less than all claims and grounds included in [the] petition. We therefore vacate the … Board's final written decision and remand for the Board to review all claims and grounds included in the petition and issue a complete final written decision.").

3. The PTO Exercised a Nonexistent "Inherent" Discretionary Authority to Disregard the Remand Order

Despite the precedent and clear judicial instruction, on remand, the PTAB failed to follow the mandate. The PTAB refused to accept that the petitioner, BioDelivery, is entitled to complete final written decisions. The PTAB allowed no arguments on the merits of any of the petition challenges that had been improperly excluded from the instituted IPRs. The PTAB merely invited and allowed briefing on the procedural question of whether it would be appropriate to vacate its prior IPR institution decisions and deny the petitions in their entirety. Dismissal Order, App. 3a. In its briefing, BioDelivery explained that vacatur of the decisions to institute the IPRs would be inappropriate. Apparently agreeing with BioDelivery on that point, PTAB did not "vacate" its prior decisions to institute the IPRs. Instead, purporting to modify the decisions to institute the IPRs, the PTAB issued DORs terminating the IPRs. Dismissal Order, App. 4a-5a. In doing so, the PTAB failed to implement *SAS* in accordance with the mandate.

On remand, the PTAB did not dispute that it had already instituted the remanded IPRs. The PTAB did not dispute the existence of a PTO policy "precluding termination of a partially instituted proceeding in response to *SAS* …." DOR-165, App. 28a; DOR-168, App. 79a; DOR-169, App. 93a-94a (referencing a PTO policy disclosed in *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28, 10 (PTAB Aug. 10, 2018)). Nor did the PTAB dispute that, since *SAS*, it had consistently "expan[ded] the scope of reviews on remand to include non-instituted

claims and grounds." DOR-165, App. 28a; DOR-168, App. 80a; DOR-169, App, 94a.

Instead, the PTAB claimed to have "inherent authority to, upon reconsideration of the Petition and accompanying evidence, deny the Petition in its entirety on remand." DOR-168, App. 82a. In other words, the PTAB claimed "inherent authority" to reject *SAS*'s premise that a petitioner in an instituted IPR is normally entitled to a complete final written decision. *See* DOR-165, App. 26a; DOR-168, App. 78a; DOR-169, App. 92a. The PTAB also glossed over the requirement of section 314(d) that "[t]he determination … whether to institute an inter partes review … shall be final …." *See* DOR-165, App. 24a-25a; DOR-168, App. 76a; DOR-169, App. 90a (all stating that section 314(d) "refer[s] to the finality of an institution decision in relation to [the decision's appealability]").

Rather than comply with the mandate to implement *SAS*, the PTAB found that the Director's general statutory authority to prescribe regulations somehow empowered it to "change its determination[] whether to institute a review …." DOR-165, App. 25a; DOR-168, App. 76a; DOR-169, App. 91a. The PTAB claimed "an inherent authority to reconsider its decisions, subject to certain limitations …." DOR-165, App. 26a-27a; DOR-68, App. 77a-78a; DOR-169, App. 92a. On the strength of this alleged inherent authority, the PTAB effectively decided it would be too much work to reach final written decisions addressing each of the challenges in the underlying petitions. *See* DOR-165, App. 29a-30a; DOR-168, App. 80a-81a; DOR-169, App. 95a-96a; *see also* Dismissal Order, App. 12a ("On remand, the PTAB held that it would be inefficient and expensive to implement the Supreme Court's

decision.") (Newman, J., dissenting). Accordingly, on its own initiative, and contrary to undisputed policy, practice, and mandate, the PTAB chose to terminate the instituted IPRs, labelling those decisions as "decisions whether to institute" under section 314. DOR-165, App. 25a; DOR-168, App. 58a; DOR-169, App. 90a; *see also* Dismissal Order, 14a-15a ("[T]he PTAB declined to execute our Remand Order.") (Newman, J., dissenting).

The PTAB's self-created authority to reconsider its decisions to institute IPRs on remand is inconsistent with federal practice and procedure, the AIA, and the mandate. A mandate limits the discretion that an agency might have under other circumstances. *See Mangum v. Hallembaek*, 910 F.3d 770 (4th Cir. 2018) (holding the Bureau of Prisons erred in considering sentencing judge's opinion when it had been instructed in a remand order that that opinion was irrelevant); *see also Banks v. United States*, 721 Fed. App'x 928 (Fed Cir. 2019) (after Federal Circuit identified errors in agency findings, agency erred by adopting the same findings again and denying hearing with new evidence); *Beverly Enterprises v. N.L.R.B.*, 727 F.2d 591, 592 (6th Cir 1984) (holding that National Labor Relations Board erred in attempting to remedy error in decision itself, rather than remanding to Regional Director as instructed in the remand order).

Even the PTAB itself struggled with the legal fiction of retroactively deciding not to institute the IPRs that it had partially completed. The DORs relied on the vacated final written decisions to support the decisions allegedly "whether to institute" the IPRs in the first place. *See, e.g.*, DOR-165, App. 24a, 27a, 33a-34a, 46a-47a; DOR-168, App. 58a, 68a-69a; DOR-169, App. 94a, 96a. Directly contrary

to the Remand Order, the PTAB found that BioDelivery had "already received the benefit of our Decision to Institute in that we conducted a trial and issued a Final Decision." DOR-165, App. 27a. The PTAB cannot use its own judgment to override the Remand Order.

4. The Federal Circuit Validated the PTO's Nonexistent Inherent Discretionary Authority

BioDelivery's appeal of the DORs never made it to merits briefing. Shortly after BioDelivery noticed its appeals, the patent owner moved to dismiss, arguing that "review is barred by 35 USC § 314(d)." Dismissal Order, App. 2a. In response, the Federal Circuit consolidated the appeals and, without allowing BioDelivery to brief the merits of its appeal, the Federal Circuit incorrectly found that "BioDelivery's appeals merely challenge the Board's determination not to institute review …." *Id.*, App. 8a. On this basis, it found that, under 35 USC § 314(d), "[s]uch a decision is 'final and nonappealable.'" *Id.*

In its Dismissal Order, the Federal Circuit validated the PTO's nonexistent inherent discretionary authority to terminate an instituted IPR on its own initiative at any time. *Id.*, App. 8a ("Nothing in our Remand Order divested the [PTAB] of [discretion not to institute review]."). The Federal Circuit largely adopted the PTAB's rationale. Like the PTAB, it rejected *SAS*'s premise that a petitioner in an instituted IPR is normally entitled to a complete final written decision. *Id.* Like the PTAB, the Federal Circuit glossed over 35 USC § 314(d)'s requirement that "[t]he determination … whether to institute an inter partes review … shall be final …." *See id.*, App. 4a-5a. And like

the PTAB, the Federal Circuit found that the PTAB has an "inherent authority to reconsider [its] decisions, subject to certain limitations …." *Id.*, App. 7a. The Federal Circuit even suggested that doing the work necessary to follow the mandate and *SAS* "would contravene the Director's statutory charge to consider the efficiency of the [PTO] in conducting IPR proceedings." *Id.*, App. 9a; *but see* 35 U.S.C. § 316(b) (charging the Director to consider the efficiency of the PTO only in prescribing IPR regulations—not in conducting IPRs).

C. By Validating the PTO's Nonexistent "Inherent" Discretionary Authority, The Federal Circuit Endorsed Nullification of Judicial Authority

In her dissent to the Dismissal Order, Judge Newman highlighted some of the far-reaching problems with that order. First, she noted that, in *SAS*, this "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." Dismissal Order, App. 11a (Newman, J., dissenting).

As Judge Newman explained, "[o]ur Remand Order and instruction was to implement the Supreme Court's holding, which was 'that [the petitioner] SAS is entitled to a final written decision addressing all of the claims it has challenged.' … BioDelivery is entitled to such decision." *Id.*, App. 16a. "[T]he question [raised by BioDelivery's appeal of the DORs] is whether the PTO must comply with this court's Remand Order and implement the ruling of the Supreme Court." *Id.*, App. 12a. The answer, of course, should be "yes."

Judge Newman went on to explain that "the PTAB declined to execute our Remand Order." *Id.*, App. 14a. "[T]he PTAB discarded these three completed IPR cases as if they had never occurred." *Id.*, App. 14a-15a "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*." *Id.*, App. 15a.

Judge Newman further observed that the Dismissal Order "endorse[s] the PTAB's action, reasoning that … proceedings can be retroactively cancelled, at the PTAB's unreviewable choice." *Id.*, App. 15a-16a. As Judge Newman noted, the Dismissal Order "h[e]ld 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." *Id.*, App. 12a.

Furthermore, allowing the PTAB to de-institute an instituted IPR at its discretion undermines the statutory scheme for IPRs. Under the AIA, the PTO has the responsibility "to resolve certain validity issues by agency IPR proceeding." *Id.*, App. 16a. The AIA specified that resolution take the form of a final written decision. 35 U.S.C. § 318(a). The Dismissal Order creates a precedent that eliminates the reasonable expectation of a final written decision in an instituted IPR. For example, in the face of the Court's *SAS* holding that the petitioner is entitled to a final written decision and an order to implement that decision, the PTAB rejected the premise that a petitioner had any such entitlement. Under the Dismissal Order, the petitioner in an instituted IPR never has the right to a final written decision because the PTAB, on its own initiative, may always exercise the inherent discretionary authority to de-institute the IPR.

In fact, under the Dismissal Order, the PTAB need **never** issue a final written decision. Under the Dismissal Order, the PTAB is instead free to issue decisions terminating reviews—unconstrained by the statutory or precedential requirements of a final written decision.

In the Dismissal Order, the Federal Circuit abdicated its responsibility to ensure that the PTAB follows the law. *See Rivers v. Roadway Exp., Inc.*, 511 U.S. 298, 312 (1994) ("It is this Court's responsibility to say what a statute means, and once the Court has spoken, it is the duty of other courts to respect that understanding of the governing rule of law."). The Dismissal Order creates a precedent under which the PTO need never comply with a remand order nor implement any ruling of this Court. When faced with a mandate that it would prefer not to execute, under the Dismissal Order, the PTAB may simply de-institute an IPR and thereby nullify the mandate. Similarly, when faced with precedent that it would prefer not to implement, under the Dismissal Order, the PTAB may simply de-institute any implicated IPRs.

The Federal Circuit's abdication of its responsibility is particularly problematic here because this Court has expressly relied on the Federal Circuit's oversight authority to mitigate concerns about the constitutionality of the IPR scheme. *See 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.'"). The oversight authority is a mere chimera if the PTAB has the inherent

discretionary authority on its own initiative to de-institute any IPR when presented with a mandate or precedent it would prefer not to implement, as the precedential Dismissal Order holds.

II. AN IPR PETITIONER LOSES DUE PROCESS RIGHTS IF 35 U.S.C § 314(D) BARS APPEAL OF A TERMINATION DECISION ON REMAND

The Federal Circuit dismissed the appeal of the DORs for one reason: it had accepted the PTAB's characterization of the DORs as discretionary decisions "whether to institute an inter partes review," which are nonappealable under section 314(d). *See* Dismissal Order, App. 7a-9a (Fed. Cir. 2019). Notwithstanding the characterization, the DORs had nothing to do with institution of an IPR. Instead, the DORs terminated instituted IPRs, albeit improperly, and are plainly reviewable. Should the Court permit section 314(d) to be interpreted broadly enough to bar appeal of decisions terminating instituted IPRs, the PTAB would be able to terminate any IPR at any stage and for any reason, with no possibility of judicial review.

A. Absent An Express Statutory Bar, the Federal Circuit Has Authority to Review Decisions in IPRs, Including Decisions Terminating Instituted IPRs

The Supreme Court has repeatedly recognized "a 'strong presumption' favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015); *see also Cuozzo*, 136 S. Ct. at 2140; *SAS*, 138 S. Ct. at 1359; *Thryv*, 140 S. Ct. at 1373. In the APA, Congress expressly provided for judicial review

of administrative actions. 5 U.S.C. § 704 (both "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review."). Congress also ensured that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action …, is entitled to judicial review thereof." 5 U.S.C. § 702.

Under the AIA, the Federal Circuit has exclusive statutory authority to review IPR final written decisions. 35 U.S.C. § 141(c) ("A party to an [IPR] … who is dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) … may appeal the Board's decisions only to the … Federal Circuit."). The Federal Circuit also has exclusive statutory authority to review other decisions that dispose of an instituted IPR:

> Because § 319 does not on its face provide the exclusive means for appeal over IPR decisions not subject to the appeal bar, and § 1295(a)(4)(A) on its face provides a right to appeal, we conclude that a final decision that disposes of an IPR proceeding in the form of an adverse judgment is a "decision" from the Board with respect to IPRs under title 35 and that § 1295 provides a right to appeal a final adverse judgment.

Arthrex, Inc. v. Smith & Nephew, Inc., 880 F.3d 1345, 1349 (Fed. Cir. 2018); *see also* 28 USC § 1295(a)(4)(A). Decisions in an instituted IPR are final and appealable, even if erroneous, when they "terminate[] the IPR proceeding." *See id.* at 1348; *see also In re Arunachalam*, 824 F.3d 987, 988 (Fed. Cir. 2016); *Automated Merchandising Systems,*

Inc. v. Lee, 782 F.3d 1376, 1380-81 (Fed. Cir. 2018). As a result, a decision terminating an instituted IPR—whether or not it is called a "final written decision"—is generally subject to judicial review.

The APA provides only two exceptions to the rule that administrative agency decisions are subject to judicial review: (1) when a statute itself precludes review; or (2) when the agency action is committed to the agency discretion by law. *See* 5 U.S.C. §§ 704, 701(a). In an IPR, only a single decision is unreviewable: the initial decision "whether to institute an [IPR]" under section 314. Section 314(a) commits the decision whether to institute an IPR to the Director's discretion. *Cuozzo*, 136 S. Ct. at 2139-40 (citing 35 U.S.C. § 314(a)). Section 314(d) precludes review of decisions whether to institute an IPR. 35 U.S.C. § 314(d) (the decision "whether to institute an [IPR] … shall be final and nonappealable."). The Court has clarified that, under section 314(d), the presumption of judicial review is overcome with respect to the Office's "initial" determination whether an IPR should proceed. *Cuozzo*, 136 S. Ct. at 2140-41.

Notwithstanding this limited statutory carve-out, the Court explained that section 314(d) does not "enable the agency to act outside of its statutory limits …." *Id.* at 2141-42. "'[S]henanigans' may be properly reviewable in the context of § 319 and under the Administrative Procedures Act, which enables reviewing courts to 'set aside agency action' that is 'contrary to constitutional right,' 'in excess of statutory jurisdiction,' or 'arbitrary [and] capricious.'" *Id.* at 2142.

In the APA and the AIA, Congress gave the Federal Circuit both the power and the responsibility to review final decisions in instituted IPRs. Judicial review of decisions terminating instituted IPRs is essential to ensure fairness, consistency, and the protection of due process.

B. The PTO Has No "Inherent" Authority to Reconsider a Proper Decision to Institute an IPR

The crux of the Federal Circuit's decision not to review the DORs is its finding that the PTAB has an "inherent" authority to reconsider its original IPR institution decisions. Dismissal Order, App. 7a. The Federal Circuit noted, for example, that the PTO may deny institution of any IPR, for any reason. Dismissal Order, App. 6a. While that may be true, it is not relevant. There is no dispute that the PTO could have **initially** decided not to institute the IPRs. *See, e.g.*, Dismissal Order, App. 12a (Newman, J., dissenting) ("the question is not whether the PTO could have initially declined to institute these reviews…"). But the PTO did decide to institute the IPRs, those decisions are final, and it must abide by its decisions. The question is now whether the Board has an inherent discretionary authority to terminate instituted IPRs over the objection of a participating petitioner—and make such a termination decision nonappealable. The answer is "no."

As a threshold matter, the PTO, an administrative agency, derives its power from statute. For example, the AIA eliminated the PTO's power to conduct inter partes reexaminations and replaced it with the power to conduct IPRs. *See, e.g., Cuozzo*, 136 S. Ct. at 2137-38 (reviewing

the history of the two proceedings). Nothing in any statute gives the PTO the alleged discretionary authority to do what the PTAB did in its DORs.

With no express statutory support for a PTAB authority to reverse its decisions to institute IPRs, the Federal Circuit instead found "administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so." Dismissal Order, App. 7a. The Federal Circuit cited two sources of support for the PTAB's alleged inherent discretionary authority to terminate an instituted IPR without possibility of appeal.

First, the Federal Circuit cited the PTO's discretionary authority to decide whether to institute an IPR under section 314. Dismissal Order, App. 7a. But the PTAB exercised its discretion under section 314 years ago when it decided to institute the underlying IPRs. And the plain language of section 314 does not allow reconsideration of those decisions at the PTO's discretion. In particular, section 314(d) expressly provides that the discretionary determination whether to institute an IPR "shall be final." Accordingly, the decisions to institute the IPRs must be the end of the PTAB's decision-making process as to whether to go forward with the IPRs. And the decisions to institute the IPRs also obligated the PTAB to conduct the instituted IPRs and provide the petitioner due process rights in that process. 35 U.S.C. § 316(c) ("The [PTAB] shall, in accordance with section 6, conduct each [IPR] instituted ...."). The notion that the PTO has an ongoing right to change its decisions to institute IPRs, at its complete discretion and at any time, is inconsistent with the AIA's statutory scheme for IPRs.

Second, the Federal Circuit relied on two of its previous decisions: *Medtronic, Inc. v. Robert Bosch Healthcare Systems, Inc.,* 839 F.3d 1382 (Fed. Cir. 2016) and *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309 (Fed. Cir. 2015). *See* Dismissal Order, App. 7a-8a. Both of those decision are inapposite. Both dismissed appeals of the vacatur of review institution decisions, at patent owner's behest, early in the proceedings based on a statutory defect in the petition itself. And neither vacatur addressed patentability.

In *Medtronic*, the petitioner failed to identify all real parties in interest in its petition. *Medtronic*, 839 F.3d at 1383-84. The statute provides that an IPR petition "may be considered only if … the petition identifies all real parties in interest." 35 U.S.C. § 312(a)(2). After the petition defect was proven through post-institution discovery, and in response to the patent owner's motion, the PTAB vacated its IPR institution decision finding the IPR should never have been instituted. *Medtronic*, 839 F.3d at 1384. The Federal Circuit dismissed petitioner's appeal of the vacatur, finding the PTAB had authority to reverse an IPR institution decision in light of the petition's "failure to meet the statutory requirements … under 312(a) …." *Medtronic*, 839 F.3d at 1385. In other words, the Federal Circuit permitted the PTAB to correct the mistake of inadvertently overstepping its statutory authority, and to do so without fear of judicial review.

Similarly, in *GTNX*, the petitioner failed to disclose that, before it filed the petitions, its parent company had challenged the validity of the patents at issue in a civil action. *GTNX,* 789 F.3d at 1311. The AIA bars institution of reviews based on a petition filed after the petitioner

or real party in interest has filed such a civil action. 35 U.S.C. §§ 325(a)(1) (post grant reviews), 315(a)(1) (similar provision for IPRs). The patent owner identified this defect in a motion after institution, and the PTAB vacated its institution decision finding it lacked authority to institute the review. *GTNX,* 789 F.3d at 1311. The Federal Circuit dismissed petitioner's appeal of the vacatur, in part, finding that "it cannot be said that GTNX has a clear and indisputable right to have the proceeding continued, in the face of the otherwise-applicable proscription of § 325(a)(1) …." *Id.* at 1312. Again, the PTAB was allowed to correct an inadvertent overstep of its own statutory authority without review.

Here, in contrast to *Medtronic* and *GTNX*, the PTAB did not act to correct an inadvertent overstep of its statutory authority. In similar contrast, the PTAB did not act on a party motion based on information that was not, but should have been, disclosed in the petition. Indeed, the DORs do not even purport to "vacate" the original decisions to institute the IPRs. And unlike the *Medtronic* and *GTNX* decisions, the DORs address patentability. In fact, after the Federal Circuit vacated the final written decisions as inadequate, the DORs purported to present substantive conclusions as to patentability while simultaneously refusing to reach complete final written decisions. *See, e.g.* DOR-165, App. 31a-46a. The dismissal of the appeals of the *Medtronic* and *GTNX* decisions, which were the PTO's first decisions in those cases with the benefit of all of the information that should have been in the underlying petitions, do not foreclose review of the DORs. The Dismissal Order below is a dangerous precedent that endorses an alleged PTO authority to reconsider and reverse IPR institution decisions to avoid the work necessary to complete the IPR.

C. The DORs are Termination Decisions, Not Institution Decisions

The DORs are not decisions whether to institute IPRs. The PTAB decided to institute the IPRs years earlier, and those decisions were not at issue in the previous appeal or the mandate. The Federal Circuit vacated, not the IPR institution decisions, but the inadequate final written decisions. Dismissal Order, App. 3a ("We granted BioDelivery's motion … and vacated the Board's final written decisions in the three IPR proceedings."). The Federal Circuit's mandate to "implement the Court's decision in *SAS*" directed the PTAB to address the inadequacies of the vacated final written decisions. *See SAS*, 138 S. Ct. at 1359-60 ("[E]verything in the statute before us confirms that [petitioner] is entitled to a final written decision addressing all of the claims it has challenged ….").

Nothing in *SAS* would require—or even permit—the PTAB to revisit its IPR institution decisions. *SAS* requires the PTAB, after instituting an IPR, to address all petition challenges in a final written decision. *See Reasons for Granting the Petition § I.B.1 supra*. Section 314 "anticipates a regime where the prospect of success on a single claim justifies review of all." *SAS*, 138 S. Ct. at 1356. "[I]t doesn't matter whether the petitioner is likely to prevail on any additional claims …." *Id.* at 1356 (emphasis omitted). Indeed, the Federal Circuit found below "that *SAS* **requires institution** on all challenged claims and all challenged grounds." Remand Order, App. 143a (emphasis added). Nothing in either *SAS* or the Federal Circuit's mandate gave the PTAB any authority or discretion to refuse institution or to reconsider its prior

decisions to institute the IPRs.

Although the PTAB had no authority to reconsider its prior decisions instituting the IPRs, it labeled its DORs—which terminated instituted IPRs—as decisions whether to institute IPRs. DOR-165, App. 18a, 46a; DOR-168, App. 51a, 82a; DOR-169, App. 85a, 123a. Even the PTAB seemed to struggle with the inconsistency of this label with the contents of the DORs themselves. *See* DOR-165, App. 27a ("we describe our decision herein as reconsidering the Petition, dismissing the Petition, or denying the Petition in its entirety …."); DOR-168, App. 78a ("we label this disposition as dismissing the Petition or denying the Petition in its entirety …."); DOR-169, App. 92a ("we label our decision herein as reconsidering the Petition, dismissing the Petition, or denying the Petition in its entirety …."). Whatever label the PTAB applied, it is undisputed that the DORs terminated the instituted IPRs. *See* Dismissal Order, App. 4a ("the Board . . . terminated the proceedings"). The DORs are, therefore, termination decisions.

D. The PTO Had No Discretionary Authority to Terminate the Instituted IPRs Over Petitioner BioDelivery's Objection

The PTAB did not label the DORs—which terminated instituted IPRs—as termination decisions, possibly because it had no authority to terminate the IPRs. Under the AIA, the PTO only gains discretionary authority to terminate an IPR after all of the petitioners have exited the IPR. Section 317(a) provides that an instituted IPR "shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner

….." 35 U.S.C. § 317(a). Section 317(a) further provides that the PTO may terminate the IPR "[i]f no petitioner remains in the inter partes review." 35 U.S.C. § 317(a). For that statutory condition to have any meaning, the PTO must not have discretionary authority to terminate IPRs as long as a petitioner remains in the review. In other words, section 317(a) expressly eliminates any discretionary authority to terminate instituted IPRs over a petitioner's objections. *See Cont'l Cas. Co. v. United States*, 314 U.S. 527, 533 (1942) ("Generally speaking a 'legislative affirmative description' implies denial of the nondescribed powers."). As long as a petitioner continues to participate in an IPR, the PTO lacks discretionary authority to terminate the IPR.

Had the PTAB correctly identified the DORs as termination decisions, those decisions would have been recognized as appealable and would have been overturned. Termination decisions are subject to appeal under the proper label. And these termination decisions—issued over the objection of the petitioner—plainly exceed a limit on the PTO's authority. *See, e.g., SAS*, 138 S. Ct. at 1359 ("[J]udicial review remains available … to set aside agency action 'not in accordance with law' or 'in excess of statutory … authority or limitations.'").

E. Allowing 35 U.S.C. § 314(d) to Bar Review of Decisions on Remand Eviscerates Judicial Review of IPRs and Deprives Petitioners of Due Process

The AIA guarantees petitioners due process in instituted IPRs. The Federal Circuit's endorsement of the PTAB's flawed reasoning in the DORs would allow the PTAB to circumvent the requirements of the AIA, avoid judicial review, and deprive future petitioners of due process. Section 314(d) was never intended as a loophole to allow the PTO to disregard the Federal Circuit's mandate or judicial precedent. Appellate review is particularly essential where, as here, an agency has overstepped its statutory authority. Allowing termination of instituted IPRs to be unappealable would remove the protection of judicial review from the IPR process. The Federal Circuit's endorsement of the overbroad interpretation of section 314(d) should not be allowed to stand.

CONCLUSION

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

Respectfully submitted,

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APPENDIX

APPENDIX A — DISMISSAL ORDER AND DISSENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED AUGUST 29, 2019

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2019-1643, 2019-1644, 2019-1645

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Appellant,

v.

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

Appellee.

August 29, 2019, Decided

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

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

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

Opinion dissenting filed by *Circuit Judge* NEWMAN.

Opinion by: REYNA

Appendix A

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, 200 L. Ed. 2d 695 (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 Mono-Sol 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 Director[1] 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

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

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, 195 L. Ed. 2d 423 (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, 203 L. Ed. 2d 712 (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 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, 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.

Appendix A

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

ISSUED AS A MANDATE: August 29, 2019

Appendix A

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 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, 200 L. Ed. 2d 695 (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 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, 182 U.S. App. D.C. 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, 16 S. Ct. 291, 40 L. Ed. 414 (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, 126 U.S. App. D.C. 399 (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, 99 S. Ct. 1139, 59 L. Ed. 2d 358 (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.

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.

APPENDIX B — DECISION ON REMAND IN IPR2015-00165 OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD, DATED FEBRUARY 7, 2019

UNITED STATES PATENT
AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL
AND APPEAL BOARD

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Petitioner,

v.

AQUESTIVE THERAPEUTICS, INC.
F/K/A MONOSOL RX, LLC,

Patent Owner.

Case IPR2015-00165
Patent 8,765,167 B2

Before JACQUELINE WRIGHT BONILLA, *Acting Deputy Chief Administrative Patent Judge*, FRANCISCO C. PRATS, and ZHENYU YANG, *Administrative Patent Judges.*

PRATS, *Administrative Patent Judge.*

DECISION ON REMAND
35 U.S.C. § 144; 37 C.F.R. § 42.5(a)

Appendix B

I. INTRODUCTION

A. Summary of Decision on Remand—Denying Institution

Our reviewing court, the United States Court of Appeals for the Federal Circuit, has remanded this proceeding to this Board to implement the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *BioDelivery Sci. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018). For the reasons discussed below, pursuant to the *SAS* decision as well as the Board's authority in relation to instituting and terminating *inter partes* reviews, we reconsider our original decision to institute trial, and instead deny review of the challenges presented in the Petition, thereby terminating this proceeding.

B. Statement of the Case

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of some, but not all, of the claims of U.S. Patent No. 8,765,167 B2 (Ex. 1001, "the '167 patent").[1] Aquestive Therapeutics, formerly known as MonoSol Rx, LLC ("Patent Owner"), did not file a Preliminary Response.

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1. With the Petition under consideration herein, Petitioner filed three other petitions for inter partes review, challenging different claims of the '167 patent. Those cases are numbered IPR2015-00167, IPR2015-00168, and IPR2015-00169. No trial was instituted in IPR2015-00167. Decisions in IPR2015-00168 and IPR2015-00169 are issued concurrently herewith.

Appendix B

We instituted trial as to only one of the seven grounds of unpatentability advanced by Petitioner, and only as to a subset of the claims challenged in that unpatentability ground. *See* Paper 6, 3–4 and 31 ("Decision to Institute" or "DI"). We issued a Final Decision holding that Petitioner had not shown that the claims for which trial was instituted were unpatentable. Paper 70, 30 ("Final Decision" or "Final Dec.").

While Petitioner's appeal of our Final Decision was pending before the Federal Circuit, the Supreme Court issued the *SAS* decision, holding that if an *inter partes* review is instituted, the Board must consider the patentability of all claims challenged in the petition. *See BioDelivery v. Aquestive*, 898 F.3d at 1207–08 (citing *SAS*, 138 S. Ct. at 1355–56). Petitioner subsequently requested the Federal Circuit to remand this proceeding to the Board to consider non-instituted claims and non-instituted grounds in accordance with *SAS*, and the court granted that request. *Id.* at 1207, 1210.

On remand, we directed the parties to provide input as to whether, at this time, an appropriate course of action going forward would be to vacate our prior Decision to Institute and deny the Petition in its entirety. Paper 79, 2. The parties have completed briefing. *See* Papers 82, 83, 88, 90. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the '167 IPRs." Paper 82, 3. Patent Owner argues the opposite. Paper 83, 1.

Having considered the parties' arguments, and given the particular circumstances of this case, we modify our

Decision to Institute and instead deny the Petition in its entirety, thereby terminating this proceeding.

C. Grounds of Unpatentability

Petitioner presents the following grounds of unpatentability (Pet. 19):

Ground	Reference[s]	Basis	Challenged Claims
1	Chen[2]	§ 102(b)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
2	Chen	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
3	Chen in view of Leung[3]	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
4	Chen in view of Leung and Modern Coating[4]	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
Ground	**Reference[s]**	**Basis**	**Challenged Claims**

2. WO 00/42992 A2 (published July 27, 2000) (Ex. 1002).

3. WO 00/18365 A2 (published Apr. 6, 2000) (Ex. 1005).

5	Tapolsky[5]	§ 102(b)	1, 4, 6–9, 11, 12, 26, 27, 32, 44, 51, 65, 72, 82, and 125–127
6	Tapolsky	§ 103(a)	1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, and 125–127
7	Tapolsky in view of Modern Coating	§ 103(a)	1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, and 125–127

Petitioner supports its challenges with Declarations by Edward D. Cohen, Ph.D. ("Cohen Decl.") (Ex. 1007), and Maureen Reitman, Sc. D. ("Reitman Decl.") (Ex. 1047).

D. Related Proceedings

In addition to IPR2015-00167, IPR2015-00168, and IPR2015-00169, noted above, the parties identify a number of proceedings, within the U.S. Patent and Trademark Office as well as in district court, which involve the '167 patent as well as patents in the same family as the '167 patent. *See* Pet. 1–4; Papers 81, 87.

4. MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B. Gutoff eds., 1992) (Ex. 1009).

5. WO 99/55312 A2 (published Nov. 4, 1999) (Ex. 1003).

Appendix B

E. Reconsideration of Decision to Institute

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response] . . . 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).

As the Supreme Court explained in *SAS*, the decision whether to institute an *inter partes* review is discretionary. *See SAS*, 128 S. Ct. at 1356 ("[Section] 314(a) invests the Director with discretion on the question *whether* to institute review . . . .").[6]

Section 316(b) requires that, when prescribing regulations for conducting *inter partes* reviews, "the Director shall consider the effect of any such regulation on . . . the efficient administration of the Office. . . ." 35 U.S.C. § 316(b); *see also* 37 C.F.R. § 42.1(b) (The rules promulgated by the Director "shall be construed to secure the just, speedy, ***and inexpensive*** resolution of every proceeding.") (Emphasis added).

In the present case, as discussed below, of the seven grounds of unpatentability presented in the Petition, we determine that Petitioner failed to establish, on the merits, a reasonable likelihood of prevailing as to six of those grounds entirely (Grounds 2–7), based on either the analysis set out in the prior Decision to Institute

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

(DI 19–31), or the analysis set forth below. And as to the seventh ground (Ground 1), we previously determined that Petitioner showed a reasonable likelihood of prevailing as to only some, but not all, of the claims challenged, for the reasons discussed in our prior Decision to Institute. DI 10–19.

In its Petition, Petitioner advanced three obviousness grounds (Grounds 2–4) on a contingency basis, i.e., only if the Board found that reference(s) discussed in Ground 1 failed to disclose elements of the challenged claims. Pet 38 (Ground 2), 43-44 (Ground 3), 45 (Ground 4); DI 19–22. In our prior Decision to Institute, we determined that Petitioner established a reasonable likelihood of success in relation to some claims (claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127), but not others (claims 6–8, 32, 38, and 109), challenged in Ground 1. DI 19. Because we determined that Petitioner established a reasonable likelihood of success on a subset of claims in relation to Ground 1, and in view of Petitioner's asserted contingencies, we declined to institute in relation to that same subset of claims challenged in Grounds 2–4. DI 20–22. In this decision now, as discussed in more detail below in Section II, C–E, we address Grounds 2–4 on the merits in relation to those claims, and find that Petitioner does not establish a reasonable likelihood of success in relation to those claims and grounds.

Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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. As noted above, moreover, as to the only ground and claims for which trial was actually instituted, Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30.

Accordingly, because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

Petitioner does not persuade us (*see* Paper 82, 1–2 and 4–6) that our decision herein is contrary to the requirements of § 314(a). Here, we base our reconsideration of the original Decision to Institute only on the information presented in the Petition. The fact that Petitioner did not ultimately prevail as to the only ground and claims for which trial was actually instituted (Ground 1) simply underscores that instituting trial as to the remaining *insufficient* grounds (Grounds 2–7) at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing this proceeding's inexpensive resolution.

Petitioner also does not persuade us that § 314(d) prohibits us from reconsidering our Decision to Institute. *See* Paper 82, 3–4.

Rather than being directed to whether the Director, or the Board, may reconsider an institution decision,

both the title and the text of § 314(d) refer to the finality of an institution decision in relation to the decision's appealability. *See* 35 U.S.C. § 314(d) ("No appeal.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."). Petitioner does not cite to any specific authority, or provide persuasive argument, supporting its position that the Board, having issued an institution decision, cannot reconsider that decision afterwards.

To the contrary, the statute requires the Director to "prescribe regulations . . . establishing and governing inter partes review," 35 U.S.C. § 316(a)(4), and under those regulations, a party dissatisfied with a decision may file a request for rehearing. 37 C.F.R. § 42.71(d). Section 42.71(d) expressly contemplates rehearing an institution decision. *See* 37 C.F.R. § 42.71(d)(1), (d)(2) (providing deadline for filing a request for rehearing a decision to institute a review or a decision not to institute a review). When granting such a request, the Board may change its determination whether to institute a review outside the three-month period under 35 U.S.C. § 314(b).

The Board has in other circumstances changed its determination as to whether to institute a review outside the three-month period institution period set out under § 314(b). *See, e.g.*, *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731, Paper 29 (PTAB Oct. 26, 2017) (granting Petitioner's request for rehearing the decision denying institution and instituting an *inter partes* review); *Incyte Corp. v. Concert Pharmaceuticals, Inc.*, IPR2017-01256, Papers 13, 14 (PTAB Apr. 9, 2018) (same); *AVX Corp. v.*

Greatbatch, Ltd., IPR2015-00710, Paper 13 (PTAB Jan. 13, 2016) (same). In all those decisions, an *inter partes* review was instituted after the three-month period required in § 314(b).

Moreover, the statute governing this proceeding expressly contemplates that a proceeding can be "dismissed" after institution. *See* 35 U.S.C. § 318(a) (requiring the Board to issue a final written decision "[i]f an inter partes review is instituted and not ***dismissed***") (emphasis added). Consistent with that provision, the Board has terminated *inter partes* reviews after institution without issuing final written decisions. *See, e.g.*, *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, IPR2014-00488, Paper 61 (PTAB May 22, 2015) (vacating the decision to institute and terminating the proceeding); *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (same); *Blackberry Corp. v. MobileMedia Ideas, LLC*, IPR2013-00036, Paper 65 (PTAB Mar. 7, 2014) (*sua sponte* terminating the proceeding after institution).

Indeed, in relation to the decision by this Board in IPR2014-00488 to terminate an instituted *inter partes* review without issuing a final decision, the Federal Circuit explained that the Board "has inherent authority to reconsider its decisions [and] 'nothing in the statute or regulations applicable here . . . clearly deprives the Board of that default authority.'" *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016) (quoting *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313); *see also id.* at 1385 ("[A]dministrative agencies

possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.") (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). Thus, whether we describe our decision herein as reconsidering the Petition, dismissing the Petition, or denying the Petition in its entirety, Petitioner does not persuade us that we lack the authority to reconsider our original Decision to Institute. Moreover, Petitioner already received the benefit of our Decision to Institute in that we conducted a trial and issued a Final Decision.

Petitioner also does not persuade us that the Federal Circuit's remand decision in this case does not authorize us to reconsider our original Decision to Institute. *See* Paper 82, 6–7.

The Federal Circuit remanded the case for us "to implement the Court's decision in *SAS*." *BioDelivery v. Aquestive*, 898 F.3d at 1210. The Federal Circuit explained that "*SAS* 'requires a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.'" *Id.* at 1208 (quoting *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018)).

In implementing *SAS*, therefore, we evaluate the Petition to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. Having evaluated the Petition, we decide, for the reasons discussed herein, that we do not institute review.

Petitioner does not persuade us that reconsidering our original Decision to Institute, and thereby terminating this proceeding, is contrary to Office guidance, policy, and practice. *See* Paper 82, 7–9. We first note that the Office's *SAS* Guidance discusses only "pending trials" and does not address post-remand proceedings, like this one, in which a final decision has already been rendered. *See* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

We acknowledge Petitioner's citation to a Board decision stating that the Office's *SAS* Guidance is to be interpreted "as *precluding termination* of a partially instituted proceeding in response to *SAS Institute*." Paper 82, 8 (quoting *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28, 10 (PTAB Aug. 10, 2018)) (emphasis added by Petitioner). *ESET* is a non-precedential panel decision, however. Moreover, that case is procedurally distinguishable from this proceeding in that the decision in *ESET* cited by Petitioner issued before a final decision was rendered, in contrast to the present situation in which a final decision has not only issued, but that decision has been appealed, and the proceeding remanded to the Board.

As to cases having post-remand procedural postures similar to this proceeding, we acknowledge Petitioner's contention that "since *SAS*, the Board has consistently ordered the expansion of the scope of reviews on remand to include non-instituted claims and grounds." Paper 82, 8. All the decisions Petitioner cites, however, are non-precedential panel decisions and, moreover, are factually distinguishable from the present situation.

Appendix B

In *Nestle Purina PetCare Co. v. Oil-Dri Corp.*, the petitioner, after filing a notice of appeal with the Federal Circuit, sought remand alleging "Patent Owner committed fraud against the Board." IPR2015-00737, Paper 45 (PTAB July 31, 2018), 3. Although the Federal Circuit remanded that case pursuant to *SAS*, and did not "require the Board to address the issues of fraud or sanctions," the Board authorized briefing relating to that important issue. *Id.* at 3–4. That unique fact does not exist in this case. Unlike the present situation, moreover, the patent owner did not oppose the *SAS* remand in *Nestle*. *Id.* at 3.

More importantly, as discussed herein, of the seven grounds Petitioner presented, no ground advanced in the Petition meets the standard for institution of an *inter partes* review, except for the single ground for which trial was actually instituted, and that ground ultimately failed as to the merits. This contrasts with the situation in nearly all of the cases cited by Petitioner, in which a majority, or at least a significant portion of the originally presented grounds, was found to meet the institution standard. *See, e.g.*, *Ulthera, Inc. v. DermaFocus LLC*, IPR2016-01459, Paper 11 (PTAB Jan. 23, 2017) (originally instituted all asserted grounds for all but two claims); *Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2015-01781, Paper 7 (PTAB Feb. 3, 2016) (originally instituted six out of eight asserted grounds, but not all claims); *Baker Hughes Oil Field Operations, Inc. v. Smith Int'l, Inc.*, IPR2016-01452, Paper 13 (PTAB Feb. 6, 2017) (originally instituted three out of five asserted grounds, but not all claims); *Adidas AG v. Nike, Inc.*, IPR2016-00921, Paper 6 (PTAB Oct. 21, 2016) (originally instituted as to one of two asserted grounds).

Thus, in the cases cited by Petitioner, expansion of the scope of review required evaluation of only a few additional claims, or one or two additional unpatentability grounds. In contrast, expanding the scope of this proceeding to include originally non-instituted grounds and claims would result in conducting a trial as to six grounds for which Petitioner has not met the standard for instituting trial.

In sum, for the reasons discussed, Petitioner does not persuade us that the Board lacks the authority in this instance to reconsider its original Decision to Institute. Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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. We, therefore, reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

As noted above, moreover, as to the only ground and claims for which trial was actually instituted (Ground 1), Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30. That fact underscores that instituting trial as to the remaining insufficient grounds (Grounds 2–7) at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing this proceeding's inexpensive resolution.

II. ANALYSIS

A. The '167 Patent (Ex. 1001)

The '167 patent discloses that films incorporating a pharmaceutical agent were known to be suitably administered to mucosal membranes, such as the mouth and nose. Ex. 1001, 1:42–58. Some of those films were known, however, to suffer from particle agglomeration issues, resulting in non-uniform distribution of the active ingredient within the film. *Id.* at 1:59–62; 2:21–53. The '167 patent attributes this non-uniform distribution to the long drying times and excessive air flow conventionally used when drying the films. *Id.* at 1:62–67. Because sheets of such films usually are cut into individual doses, a non-uniform distribution of the active ingredient could result in a final individual dosage form containing insufficient active ingredient for the recommended treatment, as well as a failure to meet regulatory standards for dosage form accuracy. *Id.* at 2:1–20.

The '167 patent addresses the issue of particle agglomeration and its associated non-uniform distribution of therapeutic agent within film dosage forms by using a "selected casting or deposition method" or "controlled drying processes" known in the prior art. *Id.* at 6:21–27.

The '167 patent describes a preferred embodiment in which "the film is dried from the bottom of the film to the top of the film." *Id.* at 24:51–52. "This is accomplished by forming the film and placing it on the top side of a surface having top and bottom sides. Then, heat is initially applied to the bottom side of the film to provide the necessary

energy to evaporate or otherwise remove the liquid carrier." *Id.* at 24:59–64. "Desirably, substantially no air flow is present across the top of the film during its initial setting period, during which a solid, visco-elastic structure is formed." *Id.* at 24:52–56.

Claim 1 of the '167 patent is representative of the claims challenged in the Petition, and reads as follows:

> 1. An oral film for delivery of a desired amount of an active component comprising:
>
> an ingestible, water-soluble, polymer matrix;
>
> at least one anti-tacking agent selected from the group consisting of stearates; stearic acid; vegetable oil; waxes; a blend of magnesium stearate and sodium lauryl sodium sulfate; boric acid; surfactants; sodium benzoate; sodium acetate; sodium chloride; DL-Leucine; polyethylene glycol; sodium oleate; sodium lauryl sulfate; magnesium lauryl sulfate; talc; corn starch; amorphous silicon dioxide; syloid; metallic stearates, Vitamin E, Vitamin E TPGS, silica and combinations thereof;
>
> and a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive

> agents and combinations thereof, said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;
>
> wherein said film is self-supporting and the active component is substantially uniformly distributed, ***whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component***.

Ex. 1001, 40:62–41:22 (emphasis added to show dispositive limitation).

B. Grounds 1 and 5–7

We have previously evaluated Grounds 1 and 5–7 on the merits, either in our Decision to Institute, in our Final Decision, or in both of those decisions.

As to Ground 1, we determined initially that Petitioner had shown a reasonable likelihood of prevailing in its challenge to claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 as anticipated by Chen. DI 12–16, 31.

Ultimately, however, we found in our Final Written Decision that Petitioner had not shown by a preponderance of the evidence that Chen anticipates claims 1, 4, 11, 12,

26, 27, 44, 51, 58, 65, 72, 82, and 125–127. Final Dec. 30. In particular, we found that Petitioner had not shown that Chen describes a film meeting the requirement in claim 1 for an active component to be substantially uniformly distributed within the film, whereby the substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of the active component. *See id.* at 11–28. On remand, because we instituted trial as to this ground and claims, we do not reevaluate either our initial findings, or our ultimate findings, as to claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 in relation to Ground 1.

In Ground 1, Petitioner also challenged claims 6–8, 32, 38, and 109. *See* Pet. 19, 23–25, 27–29. In our original Decision to Institute, we determined that Petitioner had not established a reasonable likelihood of prevailing in showing that Chen anticipated the subject matter recited in those claims, and therefore declined to institute review of those claims. *See* DI 16–19. On remand, having reconsidered the Petition and accompanying evidence, we see no reason to change our analysis. We, therefore, maintain our position and, again, determine that Ground 1 does not meet the standard for instituting *inter partes* review as to claims 6–8, 32, 38, and 109.

As to Ground 5, in our original Decision to Institute, we found that Petitioner had not established a reasonable likelihood of prevailing in showing that Tapolsky anticipated the subject matter recited in the challenged claims, and therefore declined to institute review based on Ground 5. *See* DI 22–25.

Similarly, as to Grounds 6 and 7, in our original Decision to Institute, we found that Petitioner had not established a reasonable likelihood of prevailing in showing that Tapolsky rendered obvious the subject matter recited in the challenged claims, even when combined with Modern Coating. *See id.* at 26–31. Accordingly, we declined to institute review based on Grounds 6 and 7. *See id.*

On remand, having reconsidered the Petition and accompanying evidence, we see no reason to change our analysis. We, therefore, maintain our position and, again, determine that Grounds 5–7 do not meet the standard for instituting *inter partes* review.

C. Ground 2—Obviousness in view of Chen

1. Chen (Ex. 1002)

Chen discloses a dosage unit in the form of a "flexible, non-tacky, dry conveniently packaged film. Once removed from the package and placed on a mucosal surface, the mucosal surface-coat-forming film hydrates substantially immediately to form a coating on the moist surface of the mucous membrane and then disintegrates and dissolves to release the active agent from the film." Ex. 1002, 6:25–29.

Chen discloses that its films may be prepared by a "solvent casting method" shown in its Figure 2, the method using a hydrocolloid that is "completely dissolved or dispersed in water or in a water alcoholic solution under mixing to form a homogenous formulation. In addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed

or dissolved uniformly in the hydrocolloid solution." *Id.* at 15:20–23, Fig. 2.

This "homogeneous mixture" is then degassed, coated on a non- siliconized side of a polyester film, and "dried under aeration at a temperature between 40–100°C so as to avoid destabilizing the agents contained within the formulation . . . . The dry film formed by this process is a glossy, stand alone, self supporting, non-tacky and flexible film." *Id.* at 15:25–31 (citations to Fig. 2 omitted). The film may then be cut, using a die, into shapes and sizes suitable for administration as a single dosage unit. *Id.* at 16:1–7.

2. Analysis

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 2 would have been obvious in view of Chen.

As an initial matter, we note that, in our Decision to Institute, we found that Petitioner had failed to explain with adequate specificity why an ordinary artisan would have been prompted to combine the specific ingredients required by claims 6–8, 32, 38, and 109, and therefore declined to institute review of those claims for obviousness in view of Chen as presented in Ground 2. DI 20. On remand, having reconsidered the Petition and accompanying evidence, we see no reason to change our analysis. We, therefore, maintain our position and, again, determine that Ground 2 does not meet the standard for instituting *inter partes* review as to claims 6–8, 32, 38, and 109.

As to the remaining claims challenged in Ground 2, for the reasons that follow, Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the subject matter recited in claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 would have been obvious in view of Chen, based on the contentions and evidence properly advanced in Ground 2.

The two independent claims challenged in Ground 2 are claims 1 and 109. *See* Pet. 38. As discussed above, we decline to institute review of claim 109, based on the original analysis in our Decision to Institute.

Claim 1, the remaining independent claim, recites oral films for delivering a desired amount of an active component, "wherein . . . the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Ex. 1001, 41:17–22.

Petitioner contends that a film having the substantially uniform active component distribution required by claim 1 would have been obvious in view of Chen. Pet. 41–42.

Specifically, Petitioner contends that an ordinary artisan "would have been motivated to adjust the film manufacturing process to produce film featuring a distribution of active that does not vary by more than 10% of the desired amount" because, "[a]s admitted in the '167 patent, the recited uniformity was a known [regulatory] requirement." *Id.* at 41 (citing Ex. 1001, 2:16–19).

Petitioner contends that, because "Chen's process begins by forming a homogenous mixture . . . [, m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." *Id.* (citing Ex. 1002, 15:19–25, 17:6–12 (Chen); also citing Ex. 1007 ¶¶ 49, 50, 68–73 (Cohen Decl.)). Petitioner contends that, "[i]ndeed, as stated by Dr. Cohen, '[w]hen working with a homogenous or completely dissolved coating solution, like the one disclosed in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active [component]." *Id.* at 41–42 (citing Ex. 1007 ¶ 72).

We acknowledge, as Petitioner contends, and as noted above, that Chen uses a homogeneous mixture as a starting material to produce its films. *See* Ex. 1002, 4:25–31. Nonetheless, Petitioner does not explain or identify *in its Petition* the particular steps or measures disclosed or suggested in the prior art that would have led an ordinary artisan to conclude that it would have been obvious to obtain, from that starting material, a film having the uniform distribution of active component required by claim 1 of the '167 patent.

Rather than providing, *in its Petition*, the substantive rationale as to why Chen's disclosure of a homogeneous starting material, by itself, would have rendered obvious a film having the uniform active component distribution recited in claim 1 of the '167 patent, Petitioner cites to ¶¶ 49, 50, and 68–73 of the Cohen Declaration, without specific discussion of the nature of the testimony and evidence presented therein. *See* Pet. 41–42.

Appendix B

The cited paragraphs of the Cohen Declaration, in turn, cite to a number of additional allegedly prior art teachings, none of which is cited in the Petition in relation to Ground 2. *See* Ex. 1007 ¶¶ 50, 72 (Cohen Declaration citing Ex. 1009, 268 (Modern Coating)); Ex. 1007 ¶ 68 (citing Ex. 1009, 25 and Ex. 1010, 609 (Encyclopedia of Chemical Technology));[7] Ex. 1007 ¶ 69 (citing Ex. 1009, 271 and 276).

We decline to import the discussion regarding the obviousness alleged in Ground 2 from the Cohen Declaration into the Petition, based solely on the Petition's citation of certain paragraphs within that Declaration. As stated in 37 C.F.R. § 42.6(a)(3), "[a]rguments must not be incorporated by reference from one document into another document." In this instance, we find the attempt to incorporate substantive argument into the Petition particularly inappropriate, because the incorporated argument itself cites to additional evidence not discussed in the Petition in relation to Ground 2.

Moreover, we agree with our colleagues' reasoning in *Conopco, Inc. v. The Procter & Gamble Co.*, in that "[w]e decline to consider information presented in a supporting declaration, but not discussed in a petition, because, among other reasons, doing so would encourage the use of declarations to circumvent the page limits that apply to petitions." Case IPR2013-00510, slip op. at 8 (PTAB Feb. 12, 2014) (Paper 9). In that regard we note that, in the present case, the Petition is 59 pages in length, and

7. Cohen, E. & Gutoff, E., "Coating Processes, Survey," ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY, Vol. 6, pp. 606–635, Wiley (1993).

paragraphs 49, 50, and 68–73 of the Cohen Declaration provide at least four additional pages of discussion.

In addition, even considering the cited portions of the Cohen Declaration, we are not persuaded they establish a reasonable likelihood of prevailing in showing the obviousness of a film having the uniform active component distribution required by claim 1 of the '167 patent. As evidence that it would be difficult for Chen's homogeneous mixture *not* to result in a film with the uniform distribution required by claim 1 of the '167 patent, the Cohen Declaration cites Modern Coating as disclosing that "'[i]f the coating is applied uniformly, then the dryer must immobilize it and maintain its uniformity throughout the drying process. Modern precise coating applicators can do this for most coatings.'" Cohen Decl. ¶ 50 (quoting Ex. 1009, 268 (Modern Coating) (brackets added)); *see also id.* ¶ 72 (also citing Ex. 1009, 268).

We acknowledge this general disclosure in Modern Coating (not cited in Ground 2) regarding the capacity of modern applicators to achieve uniformity with respect to "most coatings." Ex. 1009, 268. We acknowledge also the Cohen Declaration's assertion that highly uniform coatings were achievable in the 1960s. Cohen Decl. ¶ 68; *see also id.* ¶ 24 ("For example, back in the 1960s, I was part of a team that produced x-ray silver halide film, which required extremely uniform distribution of active components in the film for the film to serve its intended purpose.").

The cited portions of the Cohen Declaration, however, do not identify any teaching in Modern Coating, or

elsewhere in the record, regarding the specific polymeric materials used by Chen to make its edible films, or for that matter, the materials disclosed in the '167 patent for that purpose. Although we acknowledge the general teachings cited in the Cohen Declaration regarding the alleged straightforwardness of achieving uniformity as to most coatings, those teachings contrast substantially with, and fail to recognize, the problem identified in the specification of the '167 patent and the patents cited therein, as to the issue of particle agglomeration when preparing the particular film-type of dosage forms recited in claim 1 of the '167 patent, and disclosed in Chen. *See* Ex. 1001, 1:59–2:53.

Thus, at best, the evidence advanced in the Cohen Declaration (but not discussed in the Petition in relation to Ground 2) shows that modern applicators could achieve some unspecified measure of uniformity as to "most coatings." Ex. 1009, 268. We are not persuaded that such evidence explains with sufficient detail how or why an ordinary artisan had a reasonable expectation of preparing a film having the particular degree of uniformity required by claim 1 of the '167 patent, using the specific materials disclosed in Chen.

We acknowledge the assertion in the Cohen Declaration that "numerous variables" that could be optimized in film-making and drying processes to produce uniform coatings were long known in the art. Ex. 1007 ¶ 69 (citing *id.* ¶¶ 27, 28); *see also id.* ¶¶ 70, 71, 73 (asserting that it would have been obvious to optimize Chen's process to achieve the uniform distribution of active component recited in claim 1 of the '167 patent).

Our reviewing court has explained, however, that non-specific general teachings like those advanced by the Petitioner are insufficient to support a conclusion of obviousness. In particular, similar to the situation presently before us, one circumstance in which the prior art fails to provide a reasonable expectation of success is where the art suggests "vary[ing] all parameters or try[ing] each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (emphasis omitted).

Another circumstance in which the prior art fails to provide a reasonable expectation of success, also similar to the present fact situation, is where the art suggests exploring a "general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.*

In the present case, the Cohen Declaration does not identify which of the concededly numerous parameters might be critical to achieving the uniform distribution of active component recited in claim 1 of the '167 patent, but instead provides only a general approach as to preparing a film having that property. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in the challenge to claim 1 presented in Ground 2, even considering the evidence presented in the Cohen Declaration, which was improperly incorporated by

reference into the Petition. Accordingly, for the reasons discussed, we determine that Petitioner's Ground 2 does not meet the standard for instituting *inter partes* review as to claim 1, or its dependent claims 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127.

D. Ground 3—Obviousness in view of Chen and Leung

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 3 would have been obvious in view of Chen and Leung.

Petitioner contends that the combination of Chen and Leung would have rendered obvious the subject matter recited in claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127. Pet. 43.

Petitioner, however, cites Leung only to show that an ordinary artisan would have considered the additional limitations recited in claims 26, 27, and 127 obvious features of the film suggested by Chen. *See id.* at 43–44 ("[T]o the extent the Board may believe that any element of claims 26, 27, or 127 are not expressly or inherently disclosed in Chen, these claims are obvious over Chen in view of Leung.").

Each of claims 26, 27, and 127 of the '167 patent depends from claim 1. *See* Ex. 1001, 44:38–44, 49:10–11. Each of claims 26, 27, and 127, therefore, recites a film having at least the substantially uniform distribution of active component, discussed above, required by claim 1.

Petitioner, in relying on Leung to show the obviousness of the features in dependent claims 26, 27, and 127, does not identify any specific teaching in Leung, or elsewhere in the record, that remedies the deficiency, discussed above, of Chen in relation to claim 1's uniform distribution of active component. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in showing the obviousness of claim 1, or the other claims challenged in Ground 3, even considering the further disclosures cited in Leung. Accordingly, we determine that Petitioner's Ground 3 does not meet the standard for instituting *inter partes* review as to claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127.

E. Ground 4—Obviousness in view of Chen, Leung, and Modern Coating

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 4 would have been obvious in view of Chen, Leung, and Modern Coating.

Petitioner contends that the combination of Chen, Leung, and Modern Coating would have rendered obvious the subject matter recited in claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127. Pet. 45.

Petitioner, however, cites Modern Coating only to show that an ordinary artisan would have considered the controlled drying process, recited in claims 1 and 109 as producing the film recited in those claims, an obvious

feature of the film suggested by Chen or the combination of Chen and Leung:

> To the extent the Board finds that Chen, alone or in combination with Leung, somehow fails to disclose a "controlled drying process" under the broadest reasonable interpretation of that term, as Dr. Cohen explains, it would have been obvious to the POSITA to use the "controlled drying process" disclosed in MODERN COATING to produce uniform film.

Id. at 45–46 (citing Ex. 1007 ¶ 92 (Cohen Decl.)).

Petitioner, in advancing Modern Coating in Ground 4 to show the obviousness of the controlled drying feature recited in claims 1 and 109, does not identify any specific teaching in Modern Coating, or elsewhere in the record, that remedies the deficiency, discussed above, of Chen in relation to the uniform distribution of active component recited in claim 1, as well as claim 109. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in showing the obviousness of independent claims 1 and 109, or their dependent claims challenged in Ground 4, even considering the further disclosures cited in Modern Coating.

In addition, as to claims 6–8, 32, 38, and 109, as discussed above, Petitioner does not persuade us that it has explained with adequate specificity why an ordinary artisan would have been prompted to combine the specific ingredients required by those claims. That Modern Coating might render obvious a film produced

by a controlled drying process does nothing to remedy the deficiency in Petitioner's challenge as to claims 6–8, 32, 38, and 109.

Accordingly, we determine that Petitioner's Ground 4 does not meet the standard for instituting *inter partes* review as to claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127.

III. CONCLUSION

For the reasons given, we determine that Petitioner has not established, based on the information presented in the Petition, a reasonable likelihood of prevailing in showing the unpatentability of any claim challenged in Grounds 2 through 7. For the reasons given, we also determine that Petitioner has not established, based on the information presented in the Petition, a reasonable likelihood of prevailing in showing the unpatentability of claims 6–8, 32, 38, and 109, challenged in Ground 1.

Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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. We, therefore, reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

As noted above, as to the only ground and claims for which trial was actually instituted (Ground 1, claims 1, 4,

11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127), Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30. That fact underscores that instituting trial as to the multiple remaining insufficient grounds (Grounds 2–7 in their entirety, and Ground 1 in relation to other claims) at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing this proceeding's inexpensive resolution.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Decision to Institute issued on May 20, 2015 (Paper 6) is modified according to this Decision;

FURTHER ORDERED that Petitioner's request for *inter partes* review of claims 1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 125–127of the '167 patent is denied and no *inter partes* review is instituted.

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Appendix B

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APPENDIX C — DECISION ON REMAND IN IPR2015-00168 OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD, DATED FEBRUARY 7, 2019

UNITED STATES PATENT
AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL
AND APPEAL BOARD

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Petitioner,

v.

AQUESTIVE THERAPEUTICS, INC.
F/K/A MONOSOL RX, LLC,

Patent Owner.

Case IPR2015-00168
Patent 8,765,167 B2

Before JACQUELINE WRIGHT BONILLA, *Acting Deputy Chief Administrative Patent Judge*, FRANCISCO C. PRATS and ZHENYU YANG, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge.*

DECISION ON REMAND
35 U.S.C. § 144; 37 C.F.R. § 42.5(a)

Appendix C

INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of U.S. Patent No. 8,765,167 B2 (Ex. 1001, "the '167 patent"). Petitioner asserted five grounds of unpatentability. Pet. 18–19. Aquestive Therapeutics, Inc., formerly known as Monosol Rx, LLC ("Patent Owner"), did not file a Preliminary Response. We instituted review of all challenged claims based on one ground, but denied the other four grounds on the merits. Paper 6 ("DI"), 9–19. At the completion of the trial, we sustained the patentability of all challenged claims.[1] Paper 69 ("FD"), 29.

Petitioner appealed to the U.S. Court of Appeals for the Federal Circuit. Paper 75. After the oral argument, Petitioner requested a remand to the Board to implement the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *BioDelivery Sci. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1207 (Fed. Cir. 2018). The Federal Circuit granted that request, vacated our decision, and remanded. *Id.* at 1210.

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1. Petitioner also sought *inter partes* reviews in IPR2015-00165 and IPR2015-00169, challenging certain other claims of the '167 patent. In each of those cases, we instituted review based on fewer than all the asserted grounds. *See* IPR2015-00165, Paper 6; IPR2015-00169, Paper 6. Further, in IPR2015-00165, we instituted review of some, but not all, challenged claims. *See* IPR2015-00165, Paper 6. In both cases, we sustained the patentability of all instituted claims on the instituted grounds. *See* IPR2015-00165, Paper 70; IPR2015-00169, Paper 69.

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On remand, we sought the parties' input on whether, at this time, an appropriate course of action going forward would be to vacate our prior institution Decision and deny the Petition in its entirety. Paper 76, 2. The parties have completed briefing. *See* Papers 79, 80, 85, 87. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the '167 IPRs." Paper 79, 3. Patent Owner argues the opposite. Paper 80, 1.

After considering the parties' arguments, and under the circumstances of this case, we modify our institution Decision, deny the Petition in its entirety, and terminate this proceeding.

The '167 Patent

The '167 patent relates to rapidly dissolving films incorporating anti-tacking agents and an active ingredient that is evenly distributed throughout the film. Ex. 1001, 1:18–21.

According to the '167 patent, conventional film forming techniques inherently suffer from self-aggregation and non-uniformity of active ingredients. *Id.* at 1:59–2:33. Prior attempts to overcome this problem have other disadvantages, such as rendering the actives ineffective or even harmful. *Id.* at 2:34–53. In addition, adherence between films strips is a common problem. *Id.* at 4:1–2.

The invention of the '167 patent provides "a substantially reduced occurrence of, i.e. little or no, aggregation or conglomeration of components within the

film as is normally experienced when films are formed by conventional drying methods." *Id.* at 5:63–67. It also includes anti-tacking agents in the film compositions to reduce the adherence of the films to the roof of the mouth and to one another. *Id.* at 18:64–19:13.

Illustrative Claim

Claim 16 is the sole independent claim challenged in the Petition. It is reproduced below, with added emphasis:

> 16. An oral film for delivery of a desired amount of an active component comprising:
>
> > (a) a self-supporting film having at least one surface, said film comprising:
> >
> > > (i) an ingestible, water-soluble polymer matrix; and
> >
> > > (ii) a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof; said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix

to lock- in said active in place within said matrix and maintain said substantially uniform distribution; and

(b) a coating on said at least one surface of said self-supporting film, said coating comprising at least one anti-tacking agent selected from the group consisting of stearates; stearic acid; vegetable oil; waxes; a blend of magnesium stearate and sodium lauryl sulfate; boric acid; surfactants; sodium benzoate; sodium acetate; sodium chloride; DL-Leucine; polyethylene glycol; sodium oleate; sodium lauryl sulfate; magnesium lauryl sulfate; talc; cornstarch; amorphous silicon dioxide; syloid; metallic stearates, Vitamin E, Vitamin E TPGS, silica and combinations thereof; and wherein said film is self-supporting and *the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.*

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Case History

Petitioner challenged the '167 patent based on the following grounds:

Ground	Claims	Basis	Reference(s)
1	16, 36, 48, 55, 69, 76, 86, 92, 122, 123	§ 102	Tapolsky[2]
2	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Tapolsky in view of Chen[3]
3	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Tapolsky in view of Chen and Modern Coating[4]
4	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Chen in view of Tapolsky
5	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Chen in view of Tapolsky and Modern Coating

2. Tapolsky et al., International Publication No. WO 99/55312, published November 4, 1999 (Ex. 1003, "Tapolsky").

3. Chen et al., International Publication No. WO 00/42992, published July 27, 2000 (Ex. 1002, "Chen").

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In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Edward D. Cohen (Ex. 1007).

In our institution Decision, we denied—based on substantive analyses—four out of the five asserted grounds. DI 9–15, 18. Specifically, we concluded that based on the Petition and accompanying evidence, Petitioner did not establish a reasonable likelihood it would prevail on the grounds of (1) anticipation by Tapolsky (*id.* at 9–11); (2) obviousness over Tapolsky in view of Chen (*id.* at 11–14); (3) obviousness over Tapolsky in view of Chen, and further in view of Modern Coating (*id.* at 15); and (4) obviousness over Chen in view of Tapolsky, and further in view of Modern Coating (*id.* at 18). We, however, instituted trial to review whether the combination of Chen and Tapolsky renders all challenged claims obvious. *Id.* at 16–19.

Neither party sought reconsideration of our Decision to Institute. The case proceeded. Patent Owner filed a Response (Paper 15), and Petitioner filed a Reply (Paper 34). After hearing the oral argument (Paper 68), we issued a Final Written Decision, concluding that Petitioner did not meet its burden of proving the unpatentability of any challenged claim by a preponderance of the evidence. FD 29. Specifically, we found Petitioner failed to adequately account for the limitation of "substantially uniform distribution," as required in all challenged claims. *Id.* at 16–26. We also rejected Petitioner's contention that Patent

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4. Modern Coating and Drying Technology (Edward D. Cohen & Edgar B Gutoff eds., 1992) (Ex. 1009, "Modern Coating").

Owner should be estopped from contesting the Board's findings as to Chen in *inter partes* reexamination of three patents related to the '167 patent. *Id.* at 11–15.

Petitioner filed a rehearing request, seeking redress of the collateral-estoppel issue only. Paper 70. We denied Petitioner's request. Paper 74. Petitioner appealed. Paper 75.

On February 9, 2018, the Federal Circuit heard oral argument in the appeal of this case. *BioDelivery Sci. Int'l*, 898 F.3d at 1207. Before the Federal Circuit issued an opinion on the merits, on April 24, 2018, the Supreme Court issued its decision in *SAS*, holding that a decision under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS*, 138 S. Ct. at 1355. Thereafter, Petitioner requested that the Federal Circuit remand the final decision for the Board to consider the non-instituted grounds. *BioDelivery Sci. Int'l*, 898 F.3d at 1209. The Federal Circuit granted that request, vacated our decision, and remanded the case for us "to implement the Court's decision in *SAS*." *Id.* at 1210.

ANALYSIS

Modification of Institution Decision

Overview

In our institution Decision, we denied four out of the five asserted grounds. DI 9–15, 18. Those denials were based on substantive analyses.

For Ground 1, we declined to review whether the challenged claims are anticipated by Tapolsky because Petitioner failed to show that "Tapolsky discloses, expressly or inherently, a film having a 'substantially uniform distribution' of the active." *Id.* at 10–11.

For Ground 2, we declined to review whether the challenged claims would have been obvious over Tapolsky in view of Chen because Petitioner failed to (1) properly identify the differences between the subject matter of the challenged claims and prior art; (2) sufficiently explain the reason to modify the teachings of Tapolsky with those of Chen; and (3) adequately explain how to modify Tapolsky's disclosures to arrive at the claimed subject matter with a reasonable expectation of success. *Id.* at 11–14.

For Ground 3, we declined to review whether the challenged claims would have been obvious over Tapolsky in view of Chen and Modern Coating because Petitioner failed to show the film produced according to the drying processes taught in Modern Coating did, or would necessarily, result in a film with "substantially uniform distribution" of the active. *Id.* at 15.

For Ground 5, we declined to review whether the challenged claims would have been obvious over Chen in view of Tapolsky and Modern Coating because Petitioner's entire argument is a single sentence, that is, Petitioner "incorporates by reference the discussion in Ground 3." *Id.* at 18.

On remand, after reconsideration of the Petition and accompanying evidence, we see no reason to change our

analyses. Thus, we maintain our position that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any of the claims challenged in Grounds 1–3 and 5.

Because the majority of unpatentability grounds presented in the Petition fail to meet the institution standard, instituting trial at this time is not in the interest of either the efficient administration of the Office, or the inexpensive resolution of this proceeding.[5] Under the circumstances, it is appropriate that we exercise our discretion to deny the Petition in its entirety on this basis alone. *See SAS*, 128 S. Ct. at 1356 (explaining that the decision whether to institute an *inter partes* review is discretionary); *see also* 35 U.S.C. § 316(b) (mandating that, when prescribing regulations to conduct *inter partes* reviews, "the Director shall consider the effect of any such regulation on . . . the efficient administration of the Office"); 37 C.F.R. § 42.1(b) (requiring *inter partes* reviews be conducted "to secure the just, speedy, and inexpensive resolution of every proceeding").

Nonetheless, as discussed in more detail below, we address the single ground previously instituted (Ground

5. This is especially so because, at the completion of trial on Ground 4, we concluded that Petitioner did not meet its burden to show the unpatentability of the challenged claims. FD 29. Although we do not rely on information developed during trial in this Decision, the fact that Petitioner ultimately did not prevail as to the only ground for which trial was actually instituted underscores that instituting trial to include the remaining insufficient grounds (Grounds 1–3 and 5) would not be the best use of the Board's and the parties' limited resources.

4) again. For Ground 4, in the institution Decision, we stated we were persuaded that Petitioner had established a reasonable likelihood it would prevail on showing that claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 would have been obvious over Chen in view of Tapolsky.[6] *Id.* at 16–18. Specifically, we stated that "we agree with the Board's previous finding" in the reexamination of U.S. Patent No. 7,824,588 ("the '588 patent"), where "the Board found Chen teaching both a 'substantially uniform distribution' of the active and a 'controlled drying process.'" *Id.* at 17.

After reconsideration of the Petition and accompanying evidence, and for the reasons explained below, we determine that the Board's prior '588 decision is insufficient to establish that Chen teaches or suggests the "substantially uniform distribution" requirement. We also find unpersuasive Petitioner's other arguments addressing this limitation. As a result, we conclude that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any of the claims challenged in Ground 4 either. Thus, we modify our institution Decision and deny the Petition in its entirety on this basis also.

Claim Construction

In the institution Decision, we construed the term "substantially uniform distribution" and its variant

6. We explained that we analyzed the ground based on Tapolsky in view of Chen separately from the ground based on Chen in view of Tapolsky because Petitioner relied on different disclosures and advanced different arguments. DI 16 n.5.

"substantially uniformly distributed" based on the express language in claim 16 that "said substantially uniform distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." DI 6.

Similarly, we stated that "given the express language in claim 16, we conclude that, under the broadest reasonable construction in light of the Specification, the phrase including the term 'controlled drying process' refers to drying with at least one controlled drying parameter, which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix and to maintain the distribution of the active so that substantially equal sized individual unit doses do not vary by more than 10% of the amount of the active." *Id.* at 8–9.

On remand, after reconsideration of the Petition and accompanying evidence, we see no reason to change our determination as to claim construction.

Prior Art Disclosures

Tapolsky relates to a water-erodible pharmaceutical carrier device suitable for delivery of pharmaceutical components to mucosal surfaces. Ex. 1003, 5:5–9. In one embodiment, the device comprises "a layered film disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in one or more of the layers." *Id.* at 5:9–13.

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Chen teaches a novel dosage unit that "includes a water-soluble hydrocolloid, mucosal surface-coat-forming film, such film including an effective dose of an active agent." Ex. 1002, 3:30–32. In one embodiment, the dosage unit "is in the form of a flexible, non-tacky, dry[,] conveniently packaged film." *Id.* at 6:24–26. Once placed on a mucosal surface, the film forms a coating on the membrane and "disintegrates and dissolves to release the active agent from the film." *Id.* at 6:26–29.

Obviousness over Chen in view of Tapolsky

We focus our analysis on claim 16, the only independent claim challenged.

Chen teaches a film for mucosal delivery, which includes "an effective dose of active agent," such as a therapeutic agent or a nutritional supplement. Ex. 1002, Abstract, 10:22–23. Petitioner contends that Chen teaches a "controlled drying process" that results in a film with "substantially uniform distribution" of the active, as required in limitation (ii) and the final wherein clause of claim 16. Pet. 35–36, 38–40, 48–49, 52–56. First, Petitioner asserts the Board previously found, in a decision on appeal in an *inter partes* reexamination of a different patent in the same family as the '167 patent, that Chen meets the uniformity requirement. *Id.* at 54 (incorporating by reference "[s]ubsection . . . 5 of Ground 2"), 9 (citing Ex. 1027, 15–17, 19), 38 (citing Ex. 1027, 17, 19). According to Petitioner, Patent Owner is estopped from contesting that finding. *Id.* at 38–40. In addition, Petitioner contends that Chen's films meet the substantially-uniform-distribution

requirement as demonstrated by visual inspection, the consistent dosage unit weight, and the homogeneity of the starting solution. *Id.* at 48–49, 54–56. We address Petitioner's arguments in turn.

Collateral Estoppel

Petitioner points out that the '167 patent "is part of a large family of patents." Pet. 1–2. One of the patents in this family, U.S. Patent No. 7,824,588 ("the '588 patent"), was reexamined (control number 95/001,753). *Id.* at 2. In the reexamination, all claims of the '588 patent were rejected and the Board affirmed the rejections. *Id.*; Ex. 1027 ("the '588 decision"). In the '588 decision, the Board found that (1) "Chen teaches controlled drying" (Ex. 1027, 17); (2) "Chen inherently discloses a film with a substantially uniform content of therapeutic active composition per unit of film" (*id.* at 15); and (3) the "weight deviation of ±0.001 [shown in Table 4 of Chen] satisfies the limitation of 'substantially uniform' active content" (*id.* at 19). Petitioner argues that because Patent Owner did not appeal the '588 decision, the Board's decision is final. Pet. 39–40. As a result, Patent Owner should be estopped "from contesting the Board's findings as to Chen." *Id.*

As an initial matter, it is unclear whether, under our current rules, *inter partes* reexamination could give rise to collateral estoppel in *inter partes* review. Even assuming the doctrine could be applied generally, we determine that it does not apply in this case because the resolution of the issue here was not essential to the final judgment in the '588 decision.

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Under the doctrine of collateral estoppel, also known as issue preclusion, a judgment on the merits in a first proceeding precludes relitigation in a second proceeding "of issues actually litigated and determined in the first [proceeding]." *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994). Issue preclusion is appropriate only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom issue preclusion is asserted had a full and fair opportunity to litigate the issue in the first action. *Id.* When applying issue preclusion, "statements regarding the scope of patent claims made in a former adjudication should be narrowly construed." *Id.* at 1466.

In the '588 decision, because Patent Owner did not argue for the patentability of any dependent claims separately, the Board resolved the issue of whether Chen met the uniformity requirement solely based on the language of claim 1. Ex. 1027, 12 ("Patent Owner does not argue for the separate patentability of any dependent claims. Accordingly, the dependent claims stand or fall with claim 1."). Claim 1 of the '588 patent, as amended during the reexamination, requires "substantially uniform content of therapeutic active composition per unit of film." *Id.* at 4. Thus, the '588 decision did not resolve the issue of whether Chen met the substantially-uniform-distribution limitation, "measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component," as required by claim 16 of the '167 patent.

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In the '588 decision, the Board stated that the weight deviation of ±0.001 shown in Table 4 of Chen "is well within the less than 10% variation of active content per film unit requirement of claim 3" of the '588 patent. *Id.* at 19. Claim 3 of the '588 patent depends from claim 1 and further recites "wherein the self-supporting therapeutic active-containing film has a variation of active content of less than 10% per film unit." Ex. 1026, 40:7–9. Still, it does not require "substantially equally sized individual unit doses," as required in claim 16 of the '167 patent. In other words, like claim 1 of the '588 patent, claim 3 of the same patent does not require the substantially uniform distribution of the active content, as defined in claim 16 of the '167 patent.

Indeed, the claim language closest to claim 16 of the '167 patent appears in claim 93 of the '588 patent, which recites "[t]he method of claim 1, further comprising forming a plurality of individual dosage units of substantially the same size, wherein the active content of individual dosage units has a variance of no more than 10%." Ex. 1026, 44:7–10. In the '588 decision, however, the Board did not separately address whether Chen taught the added limitation in claim 93. In fact, the Board did not even mention claim 93. As such, the issue of whether Chen met the substantially- uniform-distribution requirement at issue in this case was not essential to the '588 decision. Because the requirements of issue preclusion have not been met, the doctrine is inapplicable in this case.

Petitioner also brings to our attention *inter partes* reexaminations of two other patents in the same family as

the '167 patent. Pet. 2 ("Similarly, the CRU finally rejected all reexamination claims of US Patent Nos. 7,897,080 (the '080 patent, Ex. 1030) and 7,666,337 (the '337 patent, Ex. 1033). *See* Ex. 1032, Control No. 90/002,170, RAN; and Ex. 1034, Control No. 90/002,171, RAN.").

As Petitioner correctly points out, we decided whether to institute an *inter partes* review based on the information presented in the Petition. Paper 79, 1 (citing 35 U.S.C. § 314(a)). At the time of the Petition, the appeals of the '080 patent and the '337 patent reexaminations were pending before the Board. Pet. 2. Thus, even if *inter partes* reexamination could give rise to collateral estoppel in *inter partes* review, the Petition does not refer to any final Board decision related to these two reexaminations for us to apply the doctrine.

We recognize that at the time of this Decision, the Board has issued final decisions in the appeals of the '080 patent and the '337 patent reexaminations. Paper 79, 6. Thus, for the sake of completeness, we address whether those decisions possibly could have preclusive effect in this case. And we conclude they could not.

"[U]nder certain circumstances, [even] where all of the requirements of issue preclusion have been met, the doctrine will not be applied." *Freeman*, 30 F.3d at 1467. Specifically, "[p]reclusion will not be effected when the quality or effectiveness of the procedures followed in the two suits differ." *Id.* For example, issue preclusion may be inappropriate when "[t]he forum in the second action affords the party against whom preclusion is

asserted procedural opportunities in the presentation and determination of the issues that were not available in the first action and could likely result in the issue being differently determined." *Id.* at 1468. Such is the case here.

In this *inter partes* review, the availability of cross-examination of witnesses is a procedural opportunity for the parties that was not available in the prior *inter partes* reexamination proceedings. Specifically, *inter partes* reexamination proceedings are conducted essentially by the same procedure as routine examination of patent applications. 37 C.F.R. § 1.937(b). There, although submission of evidence in affidavit form is allowed (37 C.F.R. §§ 1.131, 1.132), the rules for *inter partes* reexaminations do not provide for cross-examination of those affiants. *See* 37 C.F.R. §§ 1.902–1.997. In contrast, in an *inter partes* review, witnesses presenting direct testimony by affidavit are subject to cross-examination via deposition.[7] 37 C.F.R. § 42.53. Additionally, in *inter partes* reviews, unlike in reexaminations, parties may request discovery, albeit in a more limited fashion as compared to that available in district court litigation. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013) (precedential) (outlining factors the Board considers when determining whether to

7. At the completion of trial on Ground 4, we concluded that Petitioner did not meet its burden to show the unpatentability of the challenged claims, in part because cross-examination of one of Petitioner's witnesses uncovered facts that cast doubts on her direct testimony. FD 24–25. We reiterate that we do not rely on information developed during trial in this Decision. Nevertheless, that example highlights the importance of the procedural distinctions between *inter partes* reviews and reexaminations.

authorize additional discovery in an *inter partes* review). These types of procedural distinctions weigh against applying issue preclusion here based on the '588, '080, and '337 decisions in the prior *inter partes* reexaminations. Thus, we do not apply issue preclusion here.

Our conclusion is supported by the Supreme Court's decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.* 135 S. Ct. 1293, 1302 (2015). There, the Supreme Court held that the Eighth Circuit erred in concluding that a determination by the Trademark Trial and Appeal Board (TTAB) on the issue of likelihood of confusion should not have a preclusive effect on concurrent trademark infringement litigation. *B & B Hardware*, 135 S. Ct. at 1302–1303. The Court instructed that "[o]n remand, the court should apply the following rule: So long as the other ordinary elements of issue preclusion are met, when the [trademark] usages adjudicated by the TTAB are materially the same as those before the district court, issue preclusion should apply." *Id.* at 1310.

Addressing arguments regarding the procedural differences at the TTAB and in district courts, the Court explained "there is no categorical reason to doubt the quality, extensiveness, or fairness, of the agency's procedures. In large part they are exactly the same as in federal court." *B & B v. Hargis*, 135 S. Ct. at 1309 (internal citation and quotation marks omitted). The Court noted, however, that "[i]t is conceivable, of course, that the TTAB's procedures may prove ill-suited for a particular issue in a particular case, e.g., a party may have tried to introduce material evidence but was prevented by the

TTAB from doing so, or the TTAB's bar on live testimony may materially prejudice a party's ability to present its case." *Id.*

In other words, the Court implicitly endorsed the principle that because issue preclusion "is premised on principles of fairness . . . a court is not without some discretion to decide whether a particular case is appropriate for application of the doctrine." *In re Freeman*, 30 F.3d at 1467 (citations omitted). As a result, even under *B & B Hardware*, we may exercise discretion not to apply collateral estoppel when this *inter partes* review affords Patent Owner procedural opportunities in the presentation and determination of the issues, such as the opportunity for cross- examination and discovery, that were not available in the previous *inter partes* reexaminations.[8] *See Freeman*, 30 F.3d at 1468.

Indeed, the Federal Circuit underscored as significant the same difference between an *inter partes* review under the AIA and *inter partes* reexaminations as we identified in our Final Decision. *Abbott Labs. v. Cordis Corp.*, 710 F.3d 1318 (Fed. Cir. 2013). The court explained that "the purpose of this [AIA] reform was to 'convert[ ] inter partes reexamination from an examinational to an adjudicative proceeding,' and one of its touted 'improvements' over the former proceeding is to allow the limited use of

8. We acknowledge that parties in *inter partes* reexaminations may challenge witness testimony by submitting responsive declarations. It, however, does not persuade us that, at least based on the facts before us in this case, we must give preclusive effect to those previous *inter partes* reexamination decisions.

depositions." *Id.* at 1326 (citing H.R. Rep. No. 112–98, pt. 1, at 46–47 (2011)).

In sum, for the reasons discussed above, we decline to apply the doctrine of issue preclusion in this proceeding.

"*Substantially Uniform Distribution*"

Petitioner argues that the '167 patent sets forth tests, including visual inspection and consistent dosage weight, for determining whether a film has a uniform distribution of active component. Pet. 54–56. According to Petitioner, in Chen, the uniform distribution of active component is demonstrated in Example 1 by the consistent dosage weight, and in Examples 1–8 by visual inspection. *Id.* Because Chen shows "*uniform* distribution of active in the film," Petitioner concludes, it "must satisfy the *substantially uniform* distribution required by the challenged claims." *Id.* at 55.

Specifically, Petitioner asserts that the '167 patent incorporates by reference its parent, U.S. Patent No. 7,425,292 (Ex. 1035, "the '292 patent"). *Id.* at 54 (citing Ex. 1001, 1:11–14). The '292 patent discloses:

> The uniform distribution of the components within the film was apparent by examination by either the naked eye or under slight magnification. By viewing the films it was apparent that they were substantially free of aggregation, i.e., the carrier and the actives remained substantially in place and did not

> move substantially from one portion of the film to another. Therefore, there was substantially no disparity among the amount of active found in any portion of the film.

Ex. 1035, 19:56–63.

Petitioner argues that the '167 patent, via the incorporated '292 patent, teaches that "*uniform* distribution of components, including active, can be demonstrated by visual inspection." Pet. 55–56. Petitioner refers to Chen for teaching "[a] glossy, substantially transparent, stand alone, self- supporting, non-tacky and flexible film was obtained after drying." *Id.* at 49 (citing Ex. 1002, 17:15–16), 56. According to Dr. Cohen, "[a] film that is 'substantially transparent' is one that is substantially free of aggregation when viewed by the unassisted (i.e., naked) eye or under slight magnification." Ex. 1007 ¶ 110. Thus, Petitioner asserts, the films in Examples 1–8 of Chen have uniformly distributed active component, as confirmed by visual inspection disclosed in the '292 patent. Pet. 56. They, therefore, satisfy the substantially-uniform-distribution limitation in the challenged claims. *Id.*

In addition, according to the '292 patent, because each component has a unique density, "when the components of different densities are combined in a uniform manner in a film . . . individual dosages forms from the same film of substantially equal dimensions, will contain the same mass." Ex. 1035, 20:55–60. Based on this principle, the '292 patent concludes, consistent individual dosage weight shows that the distribution of the components within the film is uniform. *Id.* at 20:53–55.

Petitioner points out that "Chen reports the weights of Example 1 film dosages as 0.028±0.001g." Pet. 55 (citing Ex. 1002, Table 4). According to Petitioner, "[r]ounding Chen's reported weights to two significant digits results in a consistent 0.03 g per film dosage with a variation of 0%." *Id.* This, Petitioner contends, demonstrates that the film according to Example 1 in Chen meets the consistent-dosage-weight test disclosed in the '292 patent, and thus, satisfies the substantially-uniform-distribution limitation in the challenged claims. Pet. 55.

We are not persuaded by either argument. Claim 16 recites that the "substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Based on the express language of the claim, we conclude that the actual amount of the active component in substantially equal sized individual unit doses of the film must be determined in order to evaluate whether the distribution of the active is substantially uniform. Petitioner does not explain how the amount of the active component in each individual unit dose can be ascertained by either visual inspection of a film or weighing the dosage units.

To be sure, the specification of the '292 patent does describe the visual inspection and the consistent-dosage-weight test as methods for determining the uniform distribution of components within the film. Ex. 1035, 19:56–63, 20:53–60. With a healthy dose of common sense, however, we question the reasonableness of Petitioner's contention that both tests are able to show the *absolute*

uniform distribution of the active in a film. *See* Pet. 55 (arguing that because Chen meets the "higher bar of uniform distribution," it must satisfy the lower standard, i.e., substantially uniform distribution).

As explained in the institution Decision, "substantially uniform distribution" is "measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." DI 6. Indeed, Petitioner proposes the same construction. Pet. 18. Yet, here, Petitioner asks us to import the visual inspection and the consistent-dosage-weight test from the specification into the challenged claims. This, we cannot do. *See In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (explaining that "while the specification should be used to interpret the meaning of a claim, courts must not import limitations from the specification into the claim") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (quotation marks and alterations omitted)).

We, again, emphasize that the express language in claim 16 requires measurement of the amount of active component in substantially equal sized individual unit doses. Thus, we are not persuaded that Chen teaches the substantially-uniform-distribution limitation merely because the films thereof are substantially transparent as shown by visual inspection, or because the weights of the dosage units are consistent.

Citing the Declaration of Dr. Cohen, Petitioner further contends that Chen teaches the substantially-uniform-distribution limitation because "Chen's process

begins by forming a homogeneous mixture," and because "[m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." Pet. 56 (citing Ex. 1007 ¶¶ 106–107, 112–115). We are not persuaded.

In making his Declaration, Dr. Cohen relies on Modern Coating, which teaches drying of thin films, including the basic principles, methods, and apparatus used. *See* Ex. 1009, 267–95. Dr. Cohen testifies that "[w]hen working with a homogenous or completely dissolved coating solution, like the one described in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active." Ex. 1007 ¶ 107 (citing Ex. 1009, 268). Dr. Cohen also states that "the role of drying in maintaining uniformity of distribution was known in the art well prior to" the earliest possible priority date of the '167 patent, and that an ordinary artisan would have been aware of the variables in the drying process, and would have been able to optimize these variables to maintain uniformity of the coating solution during drying. *Id.* ¶ 113 (citing Ex. 1009, 286), ¶ 114 (citing Ex. 1009, 268). According to Dr. Cohen, "beginning in the 1960s, my colleagues and I were able to produce film with *high degree of uniformity* of distribution of components." *Id.* ¶ 112 (emphasis added).

Dr. Cohen, however, does not assert that a skilled artisan would have been able to produce film with any particular desired degree of (or absolute) uniformity. And he does not explain what the "high degree of uniformity" he and his colleagues were able to achieve, and whether it satisfies the substantially-uniform-distribution requirement recited in claim 16 of the '167 patent, that

is, as measured by substantially equally sized individual unit doses having the active component that do not vary by more than 10% of the desired amount.

Similarly, Petitioner does not argue that the "uniform film" produced according to the drying processes taught in Modern Coating meets this limitation.[9] In addition, Dr. Cohen does not opine, Petitioner does not assert, and we do not find, that an ordinary artisan would have understood an unspecified degree of uniformity as satisfying the "substantially uniform" required in the challenged claims.

Furthermore, as Dr. Cohen points out, the variables of the drying process that are amenable to optimization are numerous. Ex. 1007 ¶ 27 (citing Ex. 1009, 286, 271). For example, Modern Coating lists key drying variables as including dry bulb temperatures (i.e., temperature of the air), the solvent content of the air, air velocities, film temperature, nozzle design and spacing, air flow return path, uniformity of velocity across the nozzle width and from nozzle to nozzle and the transverse direction, dryer insulation, humidity of the incoming air, and surface temperature of the coating. Ex. 1009, 286, 271.

Yet, neither Petitioner nor Dr. Cohen explains sufficiently which particular variables of the many would

9. Petitioner does not present any other persuasive evidence, such as its own testing data, to demonstrate that the drying processes described in Modern Coating would necessarily result in a film with "substantially uniform distribution" of the active, as required in the challenged claims. *See, e.g.*, Ex. 1009, 268 ("Modern precise coating applicators can [maintain uniformity] for *most coatings*.") (emphasis added).

have been optimized, or would have been critical to substantially uniform distribution of an active component. As such, Petitioner merely suggests that one of ordinary skill in the art would have known to "vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *See In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009). As instructed by our reviewing court, we cannot analyze obviousness with this hindsight. *See id.* Thus, we are not persuaded that Chen teaches the substantially-uniform-distribution limitation merely because it starts with a homogeneous mixture.

Because the Petition does not adequately account for the substantially-uniform-distribution limitation, Petitioner has not established a reasonable likelihood it would prevail on its assertion that claim 16, as well as claims 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123, which depend from claim 16, would have been obvious over Chen in view of Tapolsky.

The Board's Authority to Deny Petition on Remand

Citing 35 U.S.C. § 314(b), Petitioner argues that "[a] determination *whether* to institute an inter partes review must be made within three months after a preliminary response or the deadline for a preliminary response."[10] Paper 79, 3. Because the deadline for Patent Owner to

10. As Petitioner acknowledges, we timely issued our institution Decision. Paper 79, 3.

file a preliminary response was years ago, Petitioner contends that "[t]he Board cannot change its mind on 'whether to institute' now." *Id.* Petitioner also asserts that "the law does not authorize a 'do over' on determinations to institute" because the determination on whether to institute an *inter partes* review is final. *Id.* at 4 (citing 35 U.S.C. § 314(d)). We are not persuaded.

First, Petitioner misinterprets § 314(d). Both the title and the text of the section refer to the finality of an institution decision in relation to the appealability of such a decision. *See* 35 U.S.C. § 314(d) ("No appeal.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.") Petitioner does not cite to any authority or provide any persuasive argument to support its position that the Board, once issuing an institution decision, cannot reconsider that decision afterwards.

Second, Petitioner neglects that the statute requires the Director to "prescribe regulations . . . establishing and governing inter partes review." 35 U.S.C. § 316(a)(4). Under the Rules, a party dissatisfied with a decision may file a request for rehearing. 37 C.F.R. § 42.71(d). This Rule specifically contemplates rehearing an institution decision. *Id.* § 42.71(d)(1), (d)(2) (providing deadline for filing a request for rehearing a decision to institute a review or a decision not to institute a review). When granting such a request, the Board may change its determination on whether to institute a review outside the three-month period under 35 U.S.C. § 314(b).

The Board has indeed done so previously. *See, e.g.*, *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731, Paper 29 (PTAB Oct. 26, 2017) (granting Petitioner's request for rehearing the decision denying institution and instituting an *inter partes* review); *Incyte Corp. v. Concert Pharmaceuticals, Inc.*, IPR2017-01256, Paper 13, 14 (PTAB Apr. 9, 2018) (same); *AVX Corp. v. Greatbatch, Ltd.*, IPR2015-00710, Paper 13 (PTAB Jan. 13, 2016) (same). In all those decisions, an *inter partes* review was instituted after the three-month period required in 35 U.S.C. § 314(b).

Third, the statute contemplates that a proceeding can be "dismissed" after it is instituted. *See* 35 U.S.C. § 318(a) (requiring the Board to issue a final written decision if "an inter partes review is instituted and not *dismissed*") (emphasis added). As a result, the Board has, under certain circumstances, terminated a proceeding without a final written decision after instituting an *inter partes* review. *See, e.g.*, *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, IPR2014-00488, Paper 61 (PTAB May 22, 2015) (vacating the decision to institute and terminating the proceeding); *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, *Ideas, LLC*, IPR2013-00036, Paper 65 (PTAB Mar. 7, 2014) (*sua sponte* terminating the proceeding after institution).

As the Federal Circuit has explained, "administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so." *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*,

839 F.3d 1382, 1385 (Fed. Cir. 2016) (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). This principle applies to the Board, and does not, here, depend on whether we label this disposition as dismissing the Petition or denying the Petition in its entirety. *See id.* at 1386 ("[T]he Board has inherent authority to reconsider its decisions [and] 'nothing in the statute or regulations applicable here . . . clearly deprives the Board of that default authority.'") (quoting *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313 (Fed. Cir. 2015)).

Nor does the fact that the case is on remand remove our ability to reconsider our decision to institute. The Federal Circuit remanded the case for us "to implement the Court's decision in *SAS*." *BioDelivery Sci. Int'l*, 898 F.3d at 1210. It explained that "*SAS* 'requires a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.'" *Id.* at 1208 (quoting *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018)). Neither *SAS* nor the Federal Circuit's remand decision in this case requires that we must institute a review.

Indeed, under *SAS*, our previous Decision to institute runs afoul of the statute and cannot stand on its own. As a result, we must reevaluate the Petition to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. And upon reconsideration, we decide no, we don't institute.

Petitioner argues that "[t]he Board cannot reverse its determination to institute reviews based on information

presented after institution." Paper 79, 5. As detailed above, we deny institution of Ground 4 based on the Petition and accompanying evidence only. *See supra* 10–24. We acknowledge that we address in this Decision the preclusive effect of the Board's final decisions in the appeals of the '080 patent and the '337 patent reexaminations, which were not referenced in the Petition, or even available at the time the Petition was filed. *Supra* at 14. That consideration—which could only have benefitted Petitioner—is "for the sake of completeness" (*id.*), and does not affect our ultimate conclusion.

Finally, Petitioner argues that "Termination of an Instituted Review in Response to *SAS* is Contrary to Office Guidance, Policy, and Practice." Paper 79, 7. In support, Petitioner cites to the Office's Guidance on the Impact of *SAS* on AIA Trial Proceedings. *Id.* That Guidance, however, applies to "pending trials," and does not address a case, like this one, which is on remand from the Federal Circuit. *See* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

Petitioner also relies on a Board decision stating that the Guidance is to be interpreted "as *precluding termination* of a partially instituted proceeding in response to *SAS Institute*." Paper 79, 8 (citing *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28 (PTAB Aug. 10, 2018), 10) (emphasis added by Petitioner). Putting aside that *ESET* is a non-precedential panel decision, that case is procedurally distinguishable from this one. Indeed, the decision in *ESET* cited by Petitioner issued before a

final decision was rendered. In contrast, in this case, a final decision not only has issued, but has been appealed and vacated, and the proceeding has been remanded to the Board. Thus, the interpretation of the Guidance in *ESET*—like the Guidance itself—does not instruct our analysis in this case.

Petitioner cites several other cases and argues "since *SAS*, the Board has consistently ordered the expansion of the scope of reviews on remand to include non-instituted claims and grounds." Paper 79, 8. As an initial matter, all the decisions Petitioner cites are panel decisions, and thus, not binding on this panel. More importantly, those cases are factually distinguishable.

For example, in some of those cases, the Board initially instituted review of the majority of the asserted grounds. *See, e.g.*, *Ulthera, Inc. v. DermaFocus LLC*, IPR2016-01459, Paper 11 (PTAB Jan. 23, 2017) (originally instituted all asserted grounds, for all except two claims); *Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2015-01781, Paper 7 (PTAB Feb. 3, 2016) (originally instituted six out of eight asserted grounds, but not all claims); *Baker Hughes Oil Field Operations, Inc. v. Smith Int'l, Inc.*, IPR2016-01452, Paper 13 (PTAB Feb. 6, 2017) (originally instituted three out of five asserted grounds, but not all claims). In contrast, in our previous institution Decision, we instituted review of all challenged claims but only one out of five asserted grounds. As explained above, to institute on all grounds now and start the trial again would not be the best use of the Board's and the parties' limited resources. *See supra* at 8–9.

In addition, in some of those prior cases, the initial denial of institution was not, as in our previous institution Decision, based on a substantive patentability analysis, but the Board's discretion. *See, e.g.*, IPR2016-01452, Paper 13, 19–22 (denying institution of one ground under 35 U.S.C. § 325(d)); *see also* IPR2017-01738, Paper 10, 25 (exercising discretion to deny institution of one ground because the prior art asserted "was considered extensively by the Office during prosecution").

In *Adidas AG v. Nike, Inc.*, the Board initially denied institution of one of two asserted grounds, again, not based on a substantive patentability analysis in light of prior art, but because "Petitioner's arguments, citations, and claim charts fail to provide appropriate guidance as to where limitations of the challenged claims are found with particularity." IPR2016-00921, Paper 6 (PTAB Oct. 21, 2016), 22; *see also id.* at 21 (stating "the claim chart offered to point out where the features of the claim are present in the prior art spans four pages and constitutes bulk citation to portions of" the prior art, and thus, "does not provide meaningful 'particularity'"). In contrast, we denied four out of five asserted grounds in our original institution Decision based on a substantive patentability analysis that considered cited prior art, pointing out where Petitioner failed to sufficiently address a claim limitation, the reason to combine prior art teachings, or a reasonable expectation of success. DI 9–15, 18.

Lastly, in *Nestle Purina PetCare Co. v. Oil-Dri Corp.*, Petitioner, after filing a notice of appeal with the Federal Circuit, sought remand, alleging "Patent Owner committed fraud against the Board." IPR2015-00737,

Paper 45 (PTAB July 31, 2018), 2–3. Although the Federal Circuit remanded that case pursuant to *SAS*, and did not "require the Board to address the issues of fraud or sanctions," the Board authorized briefing relating to that important issue. *Id.* at 3–4. That unique fact does not exist in this case.

In sum, the Board possesses inherent authority to, upon reconsideration of the Petition and accompanying evidence, deny the Petition in its entirety on remand.

CONCLUSION

We maintain that, as explained in the original institution Decision, the majority of unpatentability grounds (Grounds 1–3 and 5) presented in the Petition fail to meet the institution standard. Under the circumstances of this this case, we exercise our discretion to deny the Petition in its entirety.

Additionally, the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing the unpatentability of claims challenged in any grounds, including Ground 4. Thus, we deny review of the Petition in its entirety on this basis also.

ORDER

Accordingly, it is

ORDERED that the Decision on institution issued on May 20, 2015 (Paper 6) is modified according to this Decision;

FURTHER ORDERED that Petitioner's request for *inter partes* review of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of the '167 patent is denied and no *inter partes* review is instituted.

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APPENDIX D —DECISION ON REMAND IN IPR2015-00169 OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD, DATED FEBRUARY 7, 2019

UNITED STATES PATENT
AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL
AND APPEAL BOARD

Case IPR2015-00169
Patent 8,765,167 B2

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Petitioner,

v.

AQUESTIVE THERAPEUTICS, INC.
F/K/A MONOSOL RX, LLC,

Patent Owner.

Before JACQUELINE WRIGHT BONILLA, *Acting Deputy Chief Administrative Patent Judge*, FRANCISCO C. PRATS, and ZHENYU YANG, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON REMAND
35 U.S.C. § 144; 37 C.F.R. § 42.5(a)

Appendix D

I. INTRODUCTION

A. Summary of Decision on Remand—Denying Institution

Our reviewing court, the United States Court of Appeals for the Federal Circuit, has remanded this proceeding to this Board to implement the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *BioDelivery Sci. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1210 (Fed. Cir. 2018). For the reasons discussed below, pursuant to the *SAS* decision as well as the Board's authority in relation to instituting and terminating *inter partes* reviews, we reconsider our original decision to institute trial, and instead deny review of the challenges presented in the Petition, thereby terminating this proceeding.

B. Statement of the Case

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of some, but not all, of the claims of U.S. Patent No. 8,765,167 B2 (Ex. 1001, "the '167 patent").[1] Aquestive Therapeutics, formerly known as MonoSol Rx, LLC ("Patent Owner"), did not file a Preliminary Response.

We instituted trial as to only one of the five grounds of unpatentability advanced by Petitioner. *See* Paper 6, 3

1. With the Petition under consideration herein, Petitioner filed three other petitions for inter partes review, challenging different claims of the '167 patent. Those cases are numbered IPR2015-00165, IPR2015-00167, and IPR2015-00168. No trial was instituted in IPR2015-00167. Decisions in IPR2015-00165 and IPR2015-00168 are issued concurrently herewith.

and 24 ("Decision to Institute" or "DI"). We issued a Final Decision holding that Petitioner had not shown that the claims for which trial was instituted were unpatentable. Paper 69, 37 ("Final Decision" or "Final Dec.").

While Petitioner's appeal of our Final Decision was pending before the Federal Circuit, the Supreme Court issued the *SAS* decision, holding that if an *inter partes* review is instituted, the Board must consider the patentability of all claims challenged in the petition. *See BioDelivery v. Aquestive*, 898 F.3d at 1207–08 (citing *SAS*, 138 S. Ct. at 1355–56). Petitioner subsequently requested the Federal Circuit to remand this proceeding to the Board to consider non-instituted claims and non-instituted grounds in accordance with *SAS*, and the court granted that request. *Id.* at 1207, 1210.

On remand, we directed the parties to provide input as to whether, at this time, an appropriate course of action going forward would be to vacate our prior Decision to Institute and deny the Petition in its entirety. Paper 77, 2. The parties have completed briefing. *See* Papers 80, 81, 86, 88. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the '167 IPRs." Paper 80, 3. Patent Owner argues the opposite. Paper 81, 1.

Having considered the parties' arguments, and given the particular circumstances of this case, we modify our Decision to Institute and instead deny the Petition in its entirety, thereby terminating this proceeding.

C. Grounds of Unpatentability

Petitioner presents the following grounds of unpatentability (Pet. 18):

Appendix D

Ground	Reference[s]	Statutory Basis	Challenged Claims
1	Tapolsky[2]	35 U.S.C. § 102(b)	17, 18, 30, 31, 37, 49, 56, 70, 77, 80, 87, 93, 110, 112, 114–116, and 124
2	Tapolsky in view of Chen[3]	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
3	Tapolsky in view of Chen and Modern Coating[4]	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
4	Chen in view of Tapolsky	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
5	Chen in view of Tapolsky and Modern Coating	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124

2. WO 99/55312 A2 (published Nov. 4, 1999) (Ex. 1003).

3. WO 00/42992 A2 (published Jul. 27, 2000) (Ex. 1002).

4. MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B Gutoff eds., 1992) (Ex. 1009).

Petitioner supports its challenges with a Declaration by Edward D. Cohen, Ph.D. ("Cohen Decl.") (Ex. 1007).

D. Related Proceedings

In addition to IPR2015-00165, IPR2015-00167, and IPR2015-00168, noted above, the parties identify a number of proceedings, within the U.S. Patent and Trademark Office as well as in district court, which involve the '167 patent as well as patents in the same family as the '167 patent. *See* Pet. 1–4; Papers 79, 85.

E. Reconsideration of Decision to Institute

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response] . . . 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).

As the Supreme Court explained in *SAS*, the decision whether to institute an *inter partes* review is discretionary. *See SAS*, 128 S. Ct. at 1356 ("[Section] 314(a) invests the Director with discretion on the question *whether* to institute review . . . .").[5]

Section 316(b) requires that, when prescribing regulations for conducting *inter partes* reviews, "the Director shall consider the effect of any such regulation

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

on . . . the efficient administration of the Office. . . ." 35 U.S.C. § 316(b); *see also* 37 C.F.R. § 42.1(b) (The rules promulgated by the Director "shall be construed to secure the just, speedy, ***and inexpensive*** resolution of every proceeding.") (Emphasis added).

In the present case, as discussed below, of the five grounds of unpatentability presented in the Petition, we determined previously that Petitioner failed to establish, on the merits, a reasonable likelihood of prevailing as to four of those grounds entirely (Grounds 1–3 and 5), based on the analysis set out in the Decision to Institute. DI 10–21, 23–24. Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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. Accordingly, we reconsider our Decision to Institute and determine it is appropriate to exercise our discretion to deny review of all challenges presented in the Petition on this basis alone.

Nonetheless, as discussed in more detail below, we address the one previously instituted ground (Ground 4) again, and determine now that Petitioner does not establish a reasonable likelihood of prevailing in its challenges based on that ground. Thus, we determine that Petitioner fails to establish a reasonable likelihood that it would prevail in relation to any of the five grounds presented in the Petition, and deny review on remand on that basis also.

Petitioner does not persuade us (*see* Paper 80, 1–2 and 4–6) that our decision herein is contrary to the requirements of § 314(a). First, we base our reconsideration of the original Decision to Institute only on the information presented in the Petition. The fact that Petitioner did not ultimately prevail as to the only ground and claims for which trial was actually instituted (Ground 4) simply underscores that instituting trial as to the remaining *insufficient* grounds (Grounds 1–3 and 5) at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing this proceeding's inexpensive resolution. In addition, as noted above, on remand, we reconsider the Petition and accompanying evidence, and for the reasons explained in Section II, C below, modify our decision and determine that Petitioner fails to establish a reasonable likelihood that it would prevail as to Ground 4, in addition to Grounds 1–3 and 5.

Petitioner also does not persuade us that § 314(d) prohibits us from reconsidering our Decision to Institute. *See* Paper 80, 3–4.

Rather than being directed to whether the Director, or the Board, may reconsider an institution decision, both the title and the text of § 314(d) refer to the finality of an institution decision in relation to the decision's appealability. *See* 35 U.S.C. § 314(d) ("No appeal.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."). Petitioner does not cite to any specific authority, or provide persuasive argument, supporting its position that the Board, having issued an institution decision, cannot reconsider that decision afterwards.

To the contrary, the statute requires the Director to "prescribe regulations . . . establishing and governing inter partes review," 35 U.S.C. § 316(a)(4), and under those regulations, a party dissatisfied with a decision may file a request for rehearing. 37 C.F.R. § 42.71(d). Section 42.71(d) expressly contemplates rehearing an institution decision. *See* 37 C.F.R. § 42.71(d)(1), (d)(2) (providing deadline for filing a request for rehearing a decision to institute a review or a decision not to institute a review). When granting such a request, the Board may change its determination whether to institute a review outside the three-month period under 35 U.S.C. § 314(b).

The Board has in other instances changed its determination as to whether to institute a review outside the three-month period institution period set out under § 314(b). *See, e.g.*, *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731, Paper 29 (PTAB Oct. 26, 2017) (granting Petitioner's request for rehearing the decision denying institution and instituting an *inter partes* review); *Incyte Corp. v. Concert Pharmaceuticals, Inc.*, IPR2017-01256, Papers 13, 14 (PTAB Apr. 9, 2018) (same); *AVX Corp. v. Greatbatch, Ltd.*, IPR2015-00710, Paper 13 (PTAB Jan. 13, 2016) (same). In all those decisions, an *inter partes* review was instituted after the three-month period required in § 314(b).

Moreover, the statute governing this proceeding expressly contemplates that a proceeding can be "dismissed" after institution. *See* 35 U.S.C. § 318(a) (requiring the Board to issue a final written decision "[i]f an inter partes review is instituted and not ***dismissed***")

(emphasis added). Consistent with that provision, the Board has terminated *inter partes* reviews after institution without issuing final written decisions. *See, e.g.*, *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, IPR2014-00488, Paper 61 (PTAB May 22, 2015) (vacating the decision to institute and terminating the proceeding); *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (same); *Blackberry Corp. v. MobileMedia Ideas, LLC*, IPR2013-00036, Paper 65 (PTAB Mar. 7, 2014) (*sua sponte* terminating the proceeding after institution).

Indeed, in relation to the decision by this Board in IPR2014-00488 to terminate an instituted *inter partes* review without issuing a final decision, the Federal Circuit explained that the Board "has inherent authority to reconsider its decisions [and] 'nothing in the statute or regulations applicable here . . . clearly deprives the Board of that default authority.'" *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016) (quoting *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313); *see also id.* at 1385 ("[A]dministrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.") (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). Thus, whether we label our decision herein as reconsidering the Petition, dismissing the Petition, or denying the Petition in its entirety, Petitioner does not persuade us that we lack the authority to reconsider our original Decision to Institute.

Petitioner also does not persuade us that the Federal Circuit's remand decision in this case does not authorize us to reconsider our original Decision to Institute. *See* Paper 80, 6–7.

The Federal Circuit remanded the case for us "to implement the Court's decision in *SAS*." *BioDelivery v. Aquestive*, 898 F.3d at 1210. The Federal Circuit explained that "*SAS* 'requires a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.'" *Id.* at 1208 (quoting *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018)).

In implementing *SAS*, therefore, we evaluate the Petition to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. Having evaluated the Petition, we decide, for the reasons discussed herein, that we do not institute review.

Petitioner does not persuade us that reconsidering our original Decision to Institute, and thereby terminating this proceeding, is contrary to Office guidance, policy, and practice. *See* Paper 80, 7–9. We first note that the Office's *SAS* Guidance discusses only "pending trials" and does not address post-remand proceedings, like this one, in which a final decision has already been rendered. *See* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

We acknowledge Petitioner's citation to a Board decision stating that the Office's *SAS* Guidance is to be

interpreted "as *precluding termination* of a partially instituted proceeding in response to *SAS Institute*." Paper 80, 8 (quoting *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28, 10 (PTAB Aug. 10, 2018)) (emphasis added by Petitioner). *ESET* is a non-precedential panel decision, however. Moreover, that case is procedurally distinguishable from this proceeding in that the decision in *ESET* cited by Petitioner issued before a final decision was rendered, in contrast to the present situation in which a final decision has not only issued, but that decision has been appealed, and the proceeding remanded to the Board.

As to cases having post-remand procedural postures similar to this proceeding, we acknowledge Petitioner's contention that "since *SAS*, the Board has consistently ordered the expansion of the scope of reviews on remand to include non-instituted claims and grounds." Paper 80, 8. All the decisions Petitioner cites, however, are non-precedential panel decisions and, moreover, are factually distinguishable from the present situation.

In *Nestle Purina PetCare Co. v. Oil-Dri Corp.*, the petitioner, after filing a notice of appeal with the Federal Circuit, sought remand alleging "Patent Owner committed fraud against the Board." IPR2015-00737, Paper 45 (PTAB July 31, 2018), 3. Although the Federal Circuit remanded that case pursuant to *SAS*, and did not "require the Board to address the issues of fraud or sanctions," the Board authorized briefing relating to that important issue. *Id.* at 3–4. That unique fact does not exist in this case. Unlike the present situation, moreover, the patent owner did not oppose the *SAS* remand in *Nestle*. *Id.* at 3.

More importantly, as discussed herein, of the five grounds Petitioner presented, no ground advanced in the Petition was held by the Decision to Institute to meet the standard for institution of an *inter partes* review, except for the single ground for which trial was actually instituted, and that ground ultimately failed as to the merits. This contrasts with the situation in nearly all of the cases cited by Petitioner, in which a majority, or at least a significant portion of the originally presented grounds, was found to meet the institution standard. *See, e.g.*, *Ulthera, Inc. v. DermaFocus LLC*, IPR2016-01459, Paper 11 (PTAB Jan. 23, 2017) (originally instituted all asserted grounds for all except two claims); *Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2015-01781, Paper 7 (PTAB Feb. 3, 2016) (originally instituted six out of eight asserted grounds, but not all claims); *Baker Hughes Oil Field Operations, Inc. v. Smith Int'l, Inc.*, IPR2016-01452, Paper 13 (PTAB Feb. 6, 2017) (originally instituted three out of five asserted grounds, but not all claims); *Adidas AG v. Nike, Inc.*, IPR2016-00921, Paper 6 (PTAB Oct. 21, 2016) (originally instituted as to one of two asserted grounds).

Thus, in the cases cited by Petitioner, expansion of the scope of review required evaluation of only a few additional claims, or one or two additional unpatentability grounds. In contrast, expanding the scope of this proceeding to include originally non-instituted grounds, without reconsidering our original Decision to Institute, would result in conducting a trial as to four grounds for which Petitioner did not meet the standard for instituting trial. We find that undertaking review as to four grounds for which the standard for institution of *inter partes*

review has not been met is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding, particularly when the only ground for which trial was actually instituted ultimately failed. *See* Final Dec. 37.

In sum, for the reasons discussed, Petitioner does not persuade us that the Board lacks the authority in this instance to reconsider its original Decision to Institute. Because four of the five unpatentability grounds (Grounds 1 and 3–5) presented by Petitioner fail to meet the standard for institution of *inter partes* review, we find that instituting trial as to those insufficient 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.

Accordingly, we reconsider our Decision to Institute and determine it is appropriate to exercise our discretion to deny review of all challenges presented in the Petition on this basis alone. Nonetheless, we address the one previously instituted ground (Ground 4) below, and determine now that Petitioner does not establish a reasonable likelihood of prevailing in any of its challenges presented in the Petition, i.e., in relation to any claims challenged in any of Grounds 1–5.

II. ANALYSIS

A. The '167 Patent (Ex. 1001)

The '167 patent discloses that films incorporating a pharmaceutical agent were known to be suitably

administered to mucosal membranes, such as the mouth and nose. Ex. 1001, 1:42–58. Some of those films were known, however, to suffer from particle agglomeration issues, resulting in non-uniform distribution of the active ingredient within the film. *Id.* at 1:59–62; 2:21–53. The '167 patent attributes this non-uniform distribution to the long drying times and excessive air flow conventionally used when drying the films. *Id.* at 1:62–67. Because sheets of such films usually are cut into individual doses, a non-uniform distribution of the active ingredient could result in a final individual dosage form containing insufficient active ingredient for the recommended treatment, as well as a failure to meet regulatory standards for dosage form accuracy. *Id.* at 2:1–20.

The '167 patent addresses the issue of particle agglomeration and its associated non-uniform distribution of therapeutic agent within film dosage forms by using a "selected casting or deposition method" or "controlled drying processes" known in the prior art. *Id.* at 6:21–27.

The '167 patent describes a preferred embodiment in which "the film is dried from the bottom of the film to the top of the film." *Id.* at 24:51–52. "This is accomplished by forming the film and placing it on the top side of a surface having top and bottom sides. Then, heat is initially applied to the bottom side of the film to provide the necessary energy to evaporate or otherwise remove the liquid carrier." *Id.* at 24:59–64. "Desirably, substantially no air flow is present across the top of the film during its initial setting period, during which a solid, visco-elastic structure is formed." *Id.* at 24:52–56.

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Claims 17 and 110 of the '167 patent are the independent claims challenged in the Petition, and read as follows:

17. A multi-layer film for delivery of a desired amount of an active component comprising:

(a) at least one first film layer comprising:

(i) an ingestible, water-soluble polymer matrix; and

(ii) at least one anti-tacking agent selected from the group consisting of stearates; stearic acid; vegetable oil; waxes; a blend of magnesium stearate and sodium lauryl sulfate; boric acid; surfactants; sodium benzoate; sodium acetate; sodium chloride; DL-Leucine; polyethylene glycol; sodium oleate; sodium lauryl sulfate; magnesium lauryl sulfate; talc; corn starch; amorphous silicon dioxide; syloid; metallic stearates, Vitamin E, Vitamin E TPGS, silica and combinations thereof; and

(b) a second film layer comprising:

(i) an ingestible, water-soluble polymer matrix; and

(ii) a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and

combinations thereof, wherein said first film layer is substantially in contact with said second film layer; said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution; and

wherein said film is self-supporting and the active component is substantially uniformly distributed, ***whereby said substantially uniform distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component***.

110. A multi-layer film for delivery of a desired amount of an active component comprising:

(a) a first film layer comprising:

(i) an ingestible, water-soluble or water-swellable polymer matrix; and

(b) at least a second film layer comprising:

(i) an ingestible, water-soluble or water-swellable polymer matrix comprising a water-soluble or swellable polymer;

wherein the first and/or second layers further comprise:

a desired amount of a substantially uniformly distributed active component, said active component being selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof; a component selected from the group consisting of an anti-tacking agent, a sweetener, a flavor, an acidulent, an oxide filler, propylene glycol, vitamin E acetate, polyacrylic acid, a preservative, a buffer, a coloring agent and
combinations thereof; and

wherein said first film layer is substantially in contact with said second film layer;

said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active component in place and maintain said substantially uniform distribution; and

wherein said film is self-supporting, ***whereby said substantially uniform distribution of said active component is measured by substantially equal sized***

> ***individual unit doses which do not vary by more than 10% of said desired amount of said active component***.

Ex. 1001, 43:37–44:2, 47:66–48:29 (emphases added).

B. Grounds 1–3 and 5

We previously evaluated grounds 1–3 and 5 on the merits in our Decision to Institute, and determined that Petitioner had not shown a reasonable likelihood of prevailing in establishing the unpatentability of any of the claims challenged in those grounds. DI 10–21, 23. On remand, having reconsidered the Petition and accompanying evidence, we see no reason to change our analysis. We, therefore, maintain our position and, again, determine that Grounds 1–3 and 5 do not meet the standard for instituting *inter partes* review.

C. Ground 4—Obviousness in view of Chen and Tapolsky

1. Chen (Ex. 1002)

Chen discloses a dosage unit in the form of a "flexible, non-tacky, dry conveniently packaged film. Once removed from the package and placed on a mucosal surface, the mucosal surface-coat-forming film hydrates substantially immediately to form a coating on the moist surface of the mucous membrane and then disintegrates and dissolves to release the active agent from the film." Ex. 1002, 6:25–29.

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Chen discloses that its films may be prepared by a "solvent casting method" shown in its Figure 2, the method using a hydrocolloid that is "completely dissolved or dispersed in water or in a water alcoholic solution under mixing to form a homogenous formulation. In addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution." *Id.* at 15:20–23, Fig. 2.

This "homogeneous mixture" is then degassed, coated on a non-siliconized side of a polyester film, and "dried under aeration at a temperature between 40–100°C so as to avoid destabilizing the agents contained within the formulation . . . . The dry film formed by this process is a glossy, stand alone, self supporting, non-tacky and flexible film." *Id.* at 15:25–31 (citations to Fig. 2 omitted). The film may then be cut, using a die, into shapes and sizes suitable for administration as a single dosage unit. *Id.* at 16:1–7.

2. Tapolsky (Ex. 1003)

Tapolsky discloses a device "for application of a pharmaceutical to mucosal surfaces. The device comprises an adhesive layer and a nonadhesive backing layer, and the pharmaceutical may be provided in either or both layers. Upon application, the device adheres to the mucosal surface, providing localized drug delivery and protection to the treatment site." Ex. 1003, Abstract. Tapolsky discloses that its device "comprises a layered film disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in either or both of the layers." *Id.* at 7:25–27.

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In Example 37, Tapolsky describes the preparation of a four-layered film composed of two non-adhesive backing layers, onto which were coated two bioadhesive layers that contained albuterol sulfate as the active agent. *Id.* at 37:5–25. The two backing layers were obtained by preparing a gel containing 79.74% water, 0.01% FD&C red dye 40, 0.05% sodium benzoate, 2.5% peppermint flavor, 13.5% hydroxyethyl cellulose, and 4.5% hydroxypropyl cellulose by weight. *Id.* at 37:4–6. The first backing film was coated onto a substrate and then dried at 80° C for 8 minutes. *Id.* at 37:6–9. The second backing film was then coated directly onto the first backing film and dried at 80° C for 8 minutes. *Id.* at 37:9–10.

The two bioadhesive layers of the film described in Example 37 of Tapolsky were obtained by preparing a gel containing 45.2% water USP, 45.3% ethyl alcohol, 1.6% hydroxyethyl cellulose, 0.6% hydroxypropyl cellulose, 2.8% polyacrylic acid Noveon® AA1 USP, 2.5% sodium carboxymethyl cellulose, 0.1 % titanium dioxide, and 1.9% albuterol sulfate by weight. *Id.* at 37:15–19. The first bioadesive layer was coated directly on top of the two-layered backing film and dried at 60° C for 8 minutes. *Id.* at 37:19–21. The second bioadhesive layer was coated directly onto the first bioadhesive layer and dried at 60° C for 20 minutes. *Id.* at 37:21–22. Tapolsky states that the final film "contained 1.46mg/cm2 albuterol sulfate . . . [and] also exhibited excellent tensile strength." *Id.* at 37:24–25.

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3. Analysis

a. Introduction

We previously evaluated ground 4 on the merits in our Decision to Institute, and determined that Petitioner had shown a reasonable likelihood of prevailing in establishing the unpatentability of the claims challenged in that ground. DI 21–23. On remand, having reconsidered the Petition and accompanying evidence, we modify our original Decision to Institute and instead determine that Ground 4 does not meet the standard for instituting *inter partes* review, for the reasons discussed below.

As to the substantially uniform distribution of active component recited in claims 17 and 110 (*see* Ex. 1001, 43:64–44:2 (claim 1); *id.* at 48:25–29 (claim 110)), Petitioner advances several rationales why the combination of Chen and Tapolsky teaches or suggests a film having that feature. Pet. 47, 52, 56–57.

In particular, Petitioner contends that under the doctrine of collateral estoppel, we must adopt the Board's finding in a prior decision in a related patent ("the '588 reexamination appeal decision"), that Chen's disclosure of a weight deviation of ±0.001 between film doses (Ex. 1002, 20:3 (Table 4)) met the requirement of no more than 10% variation of active content per film dosage unit. *See id.* at 56 (incorporating by reference "[s]ubsection 3 of Ground 2"). Petitioner also incorporates by reference subsection 3 of Ground 1. *Id.* Petitioner contends also that the visual inspection and consistent dosage weight described in Chen

(Ex. 1002, 17:15–16, 20:3), as well as the homogeneity of the starting solution (*id.* at 15:19–25, 17:6–12), establish that Chen's films meet the substantially uniform active agent distribution requirement of claims 17 and 110. *Id.* at 56–57.

In our original Decision to Institute, we stated that, "[a]s to the substantially uniform active agent distribution required by claims 17 and 110, on the current record, in the absence of evidence to the contrary, we agree with the Board's previous finding [in the '588 reexamination appeal decision] that Chen's active agent-containing film layer possesses that feature." DI 22.

Having reconsidered the Petition and its accompanying evidence, we modify our original Decision to Institute and instead determine, for the reasons below, that the Board's prior decision in the '588 reexamination appeal decision is insufficient to establish that Chen teaches or suggests a film that meets the uniform distribution requirement of claims 17 and 110. For the reasons discussed below, we also determine that the teachings in Tapolsky and Chen cited in Ground 4 are insufficient to establish that the combination of Chen and Tapolsky teaches or suggests a film having the uniform distribution of active component required by claims 17 and 110.

b. Substantially Uniform Distribution--Collateral Estoppel

Petitioner does not persuade us that collateral estoppel applies in this instance. As an initial matter, it is unclear whether, under our current rules, *inter partes*

reexamination could give rise to collateral estoppel in *inter partes* review. Even assuming the doctrine could be applied generally, for the reasons discussed below, we determine that it does not apply in this case.

As Petitioner contends (Pet. 37–39), under the doctrine of collateral estoppel, also known as issue preclusion, a judgment on the merits in a first proceeding precludes relitigation in a second proceeding "of issues actually litigated and determined in the first [proceeding]." *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994). In *Freeman*, the court explained that the rationale underlying issue preclusion is that "a party who has litigated an issue and lost should be bound by that decision and cannot demand that the issue be decided over again." *Id.* The court set out the requirements of the doctrine as follows:

> Issue preclusion is appropriate only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) [the party against whom issue preclusion is asserted] had a full and fair opportunity to litigate the issue in the first action.

Id. In *Freeman*, the court noted in particular that "statements regarding the scope of patent claims made in a former adjudication should be narrowly construed." *Id.* at 1466.

We find that the instant situation does not meet the requirements for applying issue preclusion because

resolution of the issue in this case was not essential to the final judgment in the '588 decision, and because the issues are not identical. In particular, the limitation at issue in this proceeding is not identical to the limitation at issue in the '588 decision, and therefore was not essential to the final judgment in the '588 decision.

The limitation at issue in claims 17 and 110 of the '167 patent states that the substantially uniform distribution "is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110).

In the prior '588 decision, the Board resolved the issue of whether Chen met the uniformity requirement based on claim 1 of the '588 patent. Ex. 1027, 12 (the '588 decision).[6] In contrast to the language in claims 17 and 110 of the '167 patent, claim 1 of the '588 patent, as amended, requires only "substantially uniform content of therapeutic active composition per unit of film." Ex. 1027, 4. Thus, the '588 decision did not resolve the issue of whether Chen met the substantial uniformity requirement based on the claim language at issue in this proceeding.

We acknowledge the statement in the '588 decision that, as to claim 3 of the '588 patent, the "weight deviation" described in Example 1 of Chen "is well within the

6. In citing to the '588 decision we cite to the original page numbers of the decision, not the pages numbers entered by Petitioner as part Exhibit 1027.

less than 10% variation of active content per film unit requirement of claim 3" of the '588 patent. Ex. 1027, 19. As noted immediately above, however, the '588 decision resolved the uniformity issue based on claim 1 of the '588 patent, not on claim 3, which depends from claim 1.

Moreover, unlike claims 17 and 110 of the '167 patent, claim 3 of the '588 patent does not require the substantial uniformity to be based on substantially equal sized unit doses derived from a single film. Instead, claim 3 of the '588 patent recites only a "self-supporting therapeutic active-containing film [that] has a variation of active content of less than 10% per film unit." Ex. 1026, 40:7–9. Rather than claim 3 of the '588 patent, the claim language closest to claims 17 and 110 of the '167 patent appears in claim 93 of the '588 patent. Ex 1026, 44:7–10. Specifically, claim 93 of the '588 patent recites "[t]he method of claim 1, further comprising forming a plurality of individual dosage units of substantially the same size, wherein the active content of individual dosage units has a variance of no more than 10%." *Id.*

Claims 3 and 93 of the '588 patent are presumed to not have the same scope. *See Kraft Foods Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000) ("Under the doctrine of claim differentiation, two claims of a patent are presumptively of different scope."). Thus, even assuming that the '588 decision made findings as to claim 3 of the '588 patent, because claims 3 and 93 of the '588 patent do not have the same scope, it is apparent that the '588 decision did not resolve the issue of whether Chen met the substantial uniformity requirement at issue in this proceeding.

Petitioner also identifies *inter partes* reexaminations of two other patents in the same family as the '167 patent. Pet. 2 ("Similarly, the CRU finally rejected all reexamination claims of US Patent Nos. 7,897,080 (the '080 patent, Ex. 1030) and 7,666,337 (the '337 patent, Ex. 1033). See Ex. 1032, Control No. 90/002,170, RAN; and Ex. 1034, Control No. 90/002,171, RAN."); *see also* Paper 80, 6 (noting the finality of the '080 and '337 patent reexamination decisions).[7]

As Petitioner points out, in the present case, our decision whether to institute an *inter partes* review is based only on the information presented in the Petition. Paper 80, 1 (citing 35 U.S.C. § 314(a)). At the time of the Petition, the appeals of the '080 and '337 patent reexaminations were pending before the Board. Pet. 2. Thus, even if *inter partes* reexamination could give rise to collateral estoppel in an *inter partes* review, the Petition does not identify a final Board decision in these two reexaminations that provides a basis for us to apply the doctrine.

We recognize that, at the time of the decision herein, the Board has issued final decisions in the appeals of the '080 patent and the '337 patent reexaminations. Paper 80, 6. For the reasons discussed below, however, we are not persuaded that the final decisions in the appeals of the '080 patent and the '337 patent reexaminations, or in the '588 patent reexamination, have preclusive effect.

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7. The correct control numbers for the '080 and '337 reexaminations are 95/002,170 and 95/002,171, respectively.

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As explained in *In re Freeman*, "under certain circumstances, where all of the requirements of issue preclusion have been met, the doctrine will not be applied. Preclusion will not be effected when the quality or effectiveness of the procedures followed in the two suits differ." 30 F.3d at 1467. In particular, issue preclusion may be inappropriate when the "forum in the second action affords the party against whom preclusion is asserted procedural opportunities in the presentation and determination of the issues that were not available in the first action and could likely result in the issue being differently determined." *Id.* at 1468 (citing Restatement (Second) of Judgments § 29 (1980)).

We find that the instant *inter partes* review under the AIA offers a significant procedural opportunity to the parties that was not available in the prior *inter partes* reexamination proceeding of the '588 patent cited by Petitioner. Specifically, *inter partes* reexamination proceedings are conducted essentially by the same procedure as routine examination of patent applications. 37 C.F.R. § 1.937(b). Although normal examination procedure allows for submission of evidence in affidavit form (37 C.F.R. §§ 1.131, 1.132), the rules for *inter partes* reexaminations do not provide for cross-examination of those affiants. *See* 37 C.F.R. §§ 1.902–1.997.

In contrast, in the instant proceeding, witnesses presenting direct testimony by affidavit are subject to cross-examination via deposition. 37 C.F.R. § 42.53. Thus, the availability of cross-examination of witnesses in this *inter partes* review under the AIA is a significant

procedural opportunity for Patent Owner which is not present in the prior *inter partes* reexamination proceeding, and that procedural distinction indeed could yield a result different from that in the prior *inter partes* reexamination.

In addition, unlike in reexaminations, parties in *inter partes* reviews may request discovery, although to a more limited extent than in district court litigation. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013) (precedential) (outlining factors the Board considers when determining whether to authorize additional discovery in an *inter partes* review). This procedural distinction also weighs against applying issue preclusion in this proceeding, based on the '588, '080, and '337 decisions in the prior *inter partes* reexaminations. Accordingly, for the reasons discussed, Petitioner does not persuade us that the doctrine of collateral estoppel is applicable in this proceeding.

c. Substantially Uniform Distribution—Tapolsky

In Ground 4, Petitioner incorporates by reference subsection 3 of Ground 1 in asserting that the combination of Chen and Tapolsky teaches or suggests a film having the substantially uniform active component distribution required by claims 17 and 110. Pet. 56.

In subsection 3 of Ground 1, Petitioner asserts that Tapolsky describes a film having the uniform distribution

of active component required by claims 17 and 110 of the '167 patent. Pet. 30–31. Petitioner notes that Tapolsky reports the amount of albuterol sulfate in Example 37 to be 1.46 mg/cm2. *Id.* at 30. Petitioner contends that, "[g]iven the reported degree of certainty (i.e., out to the second decimal place), the greatest difference in the amount of active per centimeter squared would be, at most, 0.009 mg (i.e., the difference between 1.464 mg/cm2 and 1.455 mg/cm2)." *Id.*

Thus, Petitioner contends, "the greatest variation in active between equally sized individual unit doses of Tapolsky's film that could exist given the reported value, is 0.61% (0.009 mg/cm2 divided by 1.46 mg/cm2), a value well within" the variation limitation of claims 17 and 110. *Id.* at 30–31 (citing Ex. 1007 ¶ 103 (Cohen Decl.)). Petitioner contends that "[t]his percentage does not change with unit size." *Id.* at 31.

Petitioner does not persuade us that Tapolsky expressly or inherently describes a film having the uniform distribution of active agent required by claims 17 and 110 of the '167 patent. Petitioner does not direct us to disclosures in Tapolsky that describe anything specific about whether the albuterol sulfate was uniformly distributed within the film prepared in Example 37.

We note that Tapolsky describes the concentration of albuterol sulfate per cm2 in Example 37's film to two decimal places. That concentration can be determined, however, by simply dividing the mass of the albuterol sulfate in the film by the total area of the final film.

Although that calculation describes the final concentration of albuterol within the film of Example 37, Petitioner does not persuade us that it demonstrates an inherent uniform distribution of albuterol sulfate within that film. Petitioner does not direct us to any disclosure in Tapolsky explaining how the amount of albuterol sulfate per cm2 was determined, in a way that would demonstrate inherently the uniform distribution required by claims 17 and 110 of the '167 patent. Nor does Petitioner direct us to any disclosure in which Tapolsky divides its film into substantially equal sized dosage units and determines the amount of active agent within those units. Accordingly, having considered the contentions in subsection 3 of Ground 1, Petitioner does not persuade us that Tapolsky describes, teaches, or suggests, a film having the uniform distribution of active component required by claims 17 and 110 of the '167 patent.

d. Substantially Uniform Distribution—Visual Inspection

Petitioner does not persuade us that Chen inherently describes films meeting the substantial uniformity of active component distribution required by claims 17 and 110 of the '167 patent, based only on the visual appearance of the films.

Petitioner contends initially that, because Chen describes its dried composition as a "glossy, substantially transparent, stand alone, self-supporting, non-tacky and flexible film," Chen necessarily meets the substantially uniform distribution of active component required by

claims 17 and 110. Pet. 56 (citing Ex. 1002, 17:15–16 (Chen)). Petitioner explains that the '167 patent incorporates the '292 patent (Ex. 1035)[8] by reference. Pet. 56 (citing Ex. 1001, 1:11–14). Accordingly, Petitioner reasons, because the wholly incorporated '292 patent states that uniformity of distribution of active component can be determined by visual inspection, Chen's description of the visual appearance of a uniform film lacking apparent aggregations demonstrates that Chen's film meets the uniform active component distribution required by claims 17 and 110 of the '167 patent. Pet. 56 (citing Ex. 1035, 19:56–63).

We do not find this contention persuasive. Claims 17 and 110 of the '167 patent do not recite that the substantial uniformity requirement is measured by the absence of visible aggregations of substances in the claimed film. Rather, the limitation at issue in claims 17 and 110 states that the substantially uniform distribution "is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110).

Indeed, the '292 patent explains that the substantial uniformity limitation recited in claim 1 of the '167 patent requires actual testing of the individual dosage units of the film to determine the amount of active component in the film units:

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8. Robert K. Yang et al., U.S. Patent No. 7,425,292 B2 (issued Sept. 16, 2008) ("the '292 patent").

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> An alternative method of determining the uniformity of the active is to cut the film into individual doses. The individual doses may then be dissolved and tested for the amount of active in films of particular size. This demonstrates that films of substantially similar size cut from different locations on the same film contain substantially the same amount of active.

Ex. 1035, 20:62–67.

In contrast, the passage in the '292 patent regarding visual inspection cited by the Petitioner mentions nothing about the amount of active component in equal sized portions of the film, and does not state that one can determine the amount of an active component in a particular unit of the film solely by visual inspection:

> The uniform distribution of the components within the film was apparent by examination by either the naked eye or under slight magnification. By viewing the films it was apparent that they were substantially free of aggregation, i.e., the carrier and the actives remained substantially in place and did not move substantially from one portion of the film to another. Therefore, there was substantially no disparity among the amount of active found in any portion of the film.

Id. at 19:56–63.

Because visual inspection is not the measure of uniformity recited in claims 17 and 110 of the '167 patent, Petitioner does not persuade us that it is reasonable to construe the uniformity limitation at issue in those claims as being met by a visual evaluation, based on the '292 patent's disclosure that substantial uniformity (as opposed to the claimed uniformity of distribution with a variation of no more than 10%) can be verified visually. We acknowledge that the passage cited above in column 20 of the '292 patent describes actual testing of the amount of active component as an "alternative" method of verifying substantial uniformity. Ex. 1035, 20:62. The fact that the two methods of determining uniformity are described as alternatives, however, does not mean that the two methods are distinct.

In sum, Petitioner does not persuade us, for the reasons discussed, that it is reasonable to construe the measure of uniformity in claims 17 and 110 of the '167 patent, which requires a determination of the amount of active component in equal size dosage units, as being met by a method (simple visual inspection) which no evidence has shown is capable of quantifying the active component amount.

e. Substantially Uniform Distribution—Consistent Dosage Unit Weight (Chen's Example 1)

Petitioner also does not persuade us that the disclosure in Example 1 of Chen of a film weight of 0.028 "g/dosage film" with a "±SD (n)" of "0.001 (4)," inherently meets the

substantially uniform distribution of active component recited in claims 17 and 110 of the '167 patent. Pet. 56 (citing Ex. 1002, 20 (Table 4)).

Petitioner bases this contention on the first set of examples in the '292 patent (Examples A through I), in which the '292 patent weighed identically sized portions cut from the prepared films, and found the dosage weight of the portions consistently to be 0.04 grams. *Id.* (citing Ex. 1035, 20:53–62). Thus, Petitioner contends, the '292 patent, which is incorporated by reference into the '167 patent, determines substantial uniformity based on consistency in weight of same-sized portions cut from the film. *Id.* In turn, Petitioner contends, because Chen's Example 1 reports a consistent weight of "0.028 ±0.001 g/dosage film," the film of Chen's Example 1 meets the claimed substantial uniformity requirement to the extent required by the '167 patent. *Id.*

We do not find Petitioner's contentions persuasive. Consistent dosage unit weight is not the uniformity standard recited in claims 17 and 110 of the '167 patent. Rather, claims 17 and 110 expressly require a determination of the amount of active component. Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110) (the substantially uniform distribution "is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component").

Moreover, by construing the uniformity requirement of claims 17 and 110 of the '167 patent as encompassing consistent dosage unit weights, based on the examples in

the '292 patent, Petitioner improperly imports disclosure from embodiments of the incorporated '292 patent into the claims of the '167 patent. *See In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) ("[W]hile 'the specification [should be used] to interpret the meaning of a claim,' courts must not 'import[ ] limitations from the specification into the claim.' . . . [I]t is improper to 'confin[e] the claims to th[e] embodiments' found in the specification . . . .") (quoting *Phillips v. AWH Corp.,* 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc)) (citations omitted, bracketed text in internal quotes in original).

Further, although the ground of unpatentability under consideration herein is based on obviousness under § 103(a), Petitioner's contention, in this instance, is essentially that, because Chen describes a film that yields same-sized dosage units with consistent overall weights, Chen's film inherently meets the substantial uniformity requirement of claims 17 and 110 of the '167 patent. *See* Pet. 56.

It is well settled, however, that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981); *see also Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) ("The very essence of inherency is that one of ordinary skill in the art would recognize that a reference *unavoidably* teaches the property in question.") (emphasis added). We are not persuaded that Petitioner has advanced evidence to show, or explained persuasively how or why,

the allegedly same-sized dosage forms in Example 1 of Chen, that weigh the roughly same *unavoidably* contain the same amount of active ingredient, to the specific extent required by claims 17 and 110 of the '167 patent.

In sum, Petitioner does not persuade us that the consistent dosage unit weight standard is the standard of uniformity required by claims 17 and 110 of the '167 patent. Nor are we persuaded that Petitioner has established that the consistent dosage unit weight standard inherently meets the uniformity requirement recited in claims 17 and 110 of the '167 patent. Accordingly, we find that Petitioner has not shown that Chen's disclosure in Example 1, of a film that yields four dosage units having a mean dosage unit weight of 0.028 grams and a standard deviation of ± 0.001, is an inherent disclosure of a film with a substantially uniform distribution of the active component, where the substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of said active component, as required by claims 17 and 110.

f. Substantially Uniform Distribution—Forming Film From Homogeneous Solution

Petitioner contends that, because Chen's process "begins by forming a homogen[e]ous mixture[,] . . . [m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." Pet. 56–57 (citing

Ex. 1007 ¶¶ 108–109, 114–117) (Cohen Decl.)).[9] Petitioner contends that, "as Dr. Cohen stated, '[w]hen working with a homogenous or completely dissolved coating solution, like the one described in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active.'" Pet. 57 (citing Ex. 1007 ¶ 109).

We acknowledge Chen's disclosure that its films were formed from "uniform" solutions in which the ingredients "were uniformly dispersed or dissolved." Ex. 1002, 17:6–11; *see also id.* at 17:27–28 ("a homogeneous mixture of ingredients was prepared in a coating solution"). We acknowledge Dr. Cohen's testimony regarding an ordinary artisan's difficulty in not obtaining, from the homogeneous solutions described in Chen, a film with a uniform content of active component. Ex. 1007 ¶ 109 (citing Ex. 1009, 268 ("Modern Coating")).[10] We acknowledge also Dr. Cohen's testimony that uniform distribution of ingredients in film compositions had long been an achieved objective of ordinary artisans (Ex. 1007 ¶ 114), that an ordinary artisan seeking to achieve the degree of uniformity recited in claims 17 and 110 would have been aware of "numerous variables in the drying process" (*id.* ¶ 115 (citing Ex. 1009, 286 (Modern Coating)), and, accordingly, would have been able to optimize those parameters to achieve a film meeting the uniformity requirement of claims 17 and 110 of the '167 patent (*id.* ¶¶ 116–117).

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9. Declaration of Edward D. Cohen, Ph.D. (Ex. 1007; "Cohen Declaration" or "Cohen Decl.").

10. Modern Coating and Drying Technology (Edward D. Cohen & Edgar B. Gutoff eds., 1992) (Ex. 1009).

Neither Petitioner nor Dr. Cohen, however, directs us to a clear or specific teaching in Modern Coating that the measure of "uniformity" described therein (Ex. 1009, 268) is the same measure as that required by claims 17 and 110 of the '167 patent, that is, a distribution of active component that varies by less than 10% between substantially equal size dosage units, as opposed to merely a uniform thickness. Moreover, neither Petitioner nor Dr. Cohen directs us to any clear or specific teaching in Modern Coating demonstrating that the films discussed therein actually satisfy the uniformity requirement of claims 17 and 110. Nor does Petitioner direct us to specific evidence, such as experimental test results, showing that any of the drying processes described in Modern Coating necessarily produce a film meeting the uniformity requirement of claims 17 and 110. That "[m]odern precise coating applicators can [maintain uniformity] for *most coatings*" (Ex. 1009, 268 (emphasis added)) at best demonstrates a degree of likelihood that Chen's films would meet the standard of uniformity of Modern Coatings. As noted above, however, one may not rely on probabilities or possibilities to show that a reference inherently meets a limitation. *In re Oelrich*, 666 F.2d at 581.

In addition, Petitioner does not explain specifically, in either the Petition or in the Cohen Declaration, which particular variables, of the many Dr. Cohen admits would have been recognized as amenable to optimization, would have been optimized, or would have been critical to producing the substantially uniform active component distribution required by claims 17 and 110. We find,

therefore, that Petitioner has not explained with adequate specificity how or why an ordinary artisan would have reasonably expected to be able to obtain a film having the required uniform active agent distribution. *See In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (discussing that one circumstance in which the prior art fails to provide a reasonable expectation of success is where the art suggests "vary[ing] all parameters or try[ing] each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful") (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (emphasis omitted)).

In sum, for the reasons discussed, we find that Petitioner has not shown that, based on the homogeneity of Chen's coating solutions, Chen inherently describes films that meet the uniformity requirement of claims 17 and 110, nor are we persuaded that Petitioner has shown that an ordinary artisan had a reasonable expectation of success in producing such films.

4. Conclusion—Ground 4

For the reasons discussed, Petitioner does not persuade us that the combination of Chen and Tapolsky teaches or suggests a film having the substantially uniform distribution of active component required by claims 17 and 110 of the '167 patent, which are the independent claims challenged in Ground 4. Petitioner, therefore, has not established a reasonable likelihood of

prevailing in showing the unpatentability of any of the claims challenged in Ground 4.

III. CONCLUSION

For the reasons given, we determine that Petitioner has not established, based on the information presented in the Petition, a reasonable likelihood of prevailing in showing the unpatentability of any claim challenged in Grounds 1–3 and 5. Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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.

In addition, having reevaluated the information presented in the Petition, we determine that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any claim challenged in Ground 4. For all of the reasons discussed above, we reconsider our Decision to Institute, and deny review of all challenges presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Decision to Institute issued on May 20, 2015 (Paper 6) is modified according to this Decision;

FURTHER ORDERED that Petitioner's request for *inter partes* review of claims 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124 of the '167 patent is denied and no *inter partes* review is instituted.

APPENDIX E — DENIAL OF REHEARING AND DISSENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED JANUARY 13, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2019-1643, 2019-1644, 2019-1645

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.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judges*.*

NEWMAN, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

* Circuit Judge Stoll did not participate.

Appendix E

ORDER

Appellant BioDelivery Sciences International, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by appellee Aquestive Therapeutics, Inc. The petition for rehearing and response were first referred to the panel, and thereafter, to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will be issued on January 21, 2020.

FOR THE COURT

January 13, 2020
Date

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

NEWMAN, *Circuit Judge*, dissenting from denial of the petition for rehearing *en banc*.

The court has declined to rehear this appeal *en banc*. I write because of the significance of the balance of agency and judicial authority, and the rules of procedural law in the administrative state.

The issue arises from the response of the Patent Trial and Appeal Board to the Federal Circuit's mandate and order to apply the Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). In *SAS Institute* the Supreme Court held that 35 U.S.C. § 318(a) requires that in an *inter partes* review the PTAB must decide all of the claims and grounds challenged in the petition. *Id.* at 1354–58. Since the PTAB had not met this requirement for these cases, our Remand Order instructed:

> The Court 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.' "

BioDelivery Sciences Int'l, Inc. v. Aquestive Therapeutics, Inc., 898 F.3d 1205, 1207 (Fed. Cir. 2018) ("Remand Order") (quoting *SAS Institute*, 138 S. Ct. at 1355–56).

The PTAB did not comply with the Remand Order, stating that it would be inefficient and expensive to include the additional claims and grounds:

> Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we 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.

BioDelivery Sciences Int'l, Inc. v. Aquestive Therapeutics, Inc., No. IPR2015-00165, 2019 WL 494351, at *3 (P.T.A.B. Feb. 7, 2019) ("Decision on Remand").[1]

Instead of complying with the Remand Order, the PTAB withdrew all of its past actions as to these proceedings, although past actions were not the subject of the remand. Neither this court's order nor the Supreme Court's ruling in *SAS Institute* related to aspects that had already been decided. Nonetheless, my colleagues hold that the PTAB is not required to comply with the court's Remand Order, and further hold that this non-compliance is not reviewable. This action raises critical issues of agency authority, judicial responsibility, and the constitutional plan.

Discussion

For U.S. Patent No. 8,765,167, BioDelivery Sciences International, Inc. ("BioDelivery")'s petition requested

1. This is a consolidated appeal of the PTAB's three separate decisions in IPR2015-00165, IPR2015-00168, and IPR2015-00169; citations to IPR 2015-00165 apply to all three PTAB decisions.

inter partes review of claims 1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127, citing seven prior art grounds of anticipation or obviousness. *BioDelivery Sciences Int'l, Inc. v. Monosol RX, LLC*, No. IPR2015-00165, 2015 WL 2452905, at *1–2 (P.T.A.B. May 20, 2015). On May 20, 2015 the PTAB instituted the IPR on most, but not all of the challenged claims, and on one of the prior art grounds. *Id.* at *18. The PTAB received briefing and argument and held trial, and ruled by Final Written Decision that claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 are patentable. *BioDelivery Sciences Int'l, Inc. v. Monosol RX, LLC*, No. IPR2015-00165, 2016 WL 11447939, at *14 (P.T.A.B. Mar. 24, 2016).

BioDelivery appealed, and we received briefing and argument. The Supreme Court then decided *SAS Institute*, stating that "Congress's prescribed policy here is clear: the petitioner in an inter partes review is entitled to a decision on all the claims it has challenged." 138 S. Ct. at 1358. On BioDelivery's motion, we directed the PTAB "to implement the Court's decision in *SAS*." Remand Order at 1210.

The PTAB did not comply with the Remand Order. Instead, the PTAB asked the parties for advice, and received directly opposing positions. The PTAB decided to "modify [its] Decision to Institute and instead deny the Petition in its entirety, thereby terminating [the] proceeding." Decision on Remand at *1. The PTAB "ORDERED that Petitioner's request for *inter partes* review of claims 1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 125–127 of the '167 patent is denied and no *inter partes* review is instituted." *Id.* at *12.

The court now ratifies that action. However, the America Invents Act does not include agency authority to disregard the mandate, instead the Federal Circuit's "mandate and opinion . . . shall govern the further proceedings in the case:"

> 35 U.S.C. § 144. 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.

Appellate courts may remand for further proceedings, "as may be just under the circumstances:"

> 28 U.S.C. § 2106. 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.

The further proceedings here relate to implementing *SAS Institute* as to the additional claims and grounds. The remand did not include review of the decision to institute these IPRs.

My concern is with the PTAB's position that it need not follow the court's Remand Order, for reasons of efficiency

and expense. Such agency authority cannot be discerned in the America Invents Act, and contravenes decades of constitutional jurisprudence. *E.g.*, *Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948):

> Judgments, within the powers vested in courts by the Judiciary Article of the Constitution, may not lawfully be revised, overturned or refused faith and credit by another Department of Government.

See also Plaut v. Spendthrift Farm, Inc., 514 U.S. 211, 218 (1995) ("Congress cannot vest review of the decisions of Article III courts in officials of the Executive Branch.").

In *SAS Institute* the Court reiterated 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. *See City of Cleveland v. Fed. Power Comm'n*, 561 F.2d 344, 346 (D.C. Cir. 1977) (footnotes omitted):

> 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.

Judicial authority may be manifested in orders on remand. *See 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 and to obey the directions therein without variation . . . .

The Administrative Procedure Act "directs courts to set aside agency action 'not in accordance with law' or 'in excess of statutory jurisdiction, authority, or limitations.'" *SAS Institute*, 138 S. Ct. at 1359 (quoting 5 U.S.C. §§ 706(2)(A),(C)). Agency action is bound by the mandate rule:

> The mandate rule . . . dictates that 'an inferior court has no power or authority to deviate from the mandate issued by an appellate court.' Once a question has been considered and decided by an appellate court, the issue may not be reconsidered at any subsequent stage of the litigation, save on appeal.

Banks v. United States, 741 F.3d 1268, 1276 (Fed. Cir. 2014) (citation omitted) (quoting *Briggs v. Pa. R. Co.*, 334 U.S. 304, 306 (1948)). These premises are beyond debate.

The PTAB has elsewhere recognized its obligation to comply with a judicial mandate, stating: "As an initial matter, we recognize that we are bound by the mandate on matters that the mandate addressed." *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, 2019 WL 548667, at *9 (P.T.A.B. Feb. 11, 2019).

The PTAB acknowledged an Office *SAS* Guidance on

how to proceed following the decision in *SAS Institute*. The Office *SAS* Guidance states: "for pending trials in which a panel has instituted trial only on some of the challenges raised in the petition . . . the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition."[2] "[T]he Office *SAS* Guidance is to be interpreted with the weight of Office policy as precluding termination of a partially instituted proceeding in response to *SAS Institute*." *ESET, LLC v. Finjan, Inc.*, No. IPR2017-01738, 2018 WL 3854167, at *4 (P.T.A.B. Aug. 10, 2018). Here, the PTAB mentioned the Office *SAS* Guidance but did not follow it, stating that it applies only to "pending trials" and does not apply to judicial remands. Decision on Remand at *4.

Thus the PTAB departed from not only the letter but also the spirit of the Remand Order. However, the "letter and spirit" of a mandate control actions on remand. *See SUFI Network Servs., Inc. v. United States*, 817 F.3d 773, 779 (Fed. Cir. 2016) ("[B]oth the letter and the spirit of the mandate must be considered."); *Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed. Cir. 1997) ("[A]ctions on remand should not be inconsistent with either the letter or the spirit of the mandate.").

The panel herein held that this PTAB action is not reviewable. I repeat, the court's Remand Order was not for review of the PTAB's "institution" decisions; the Remand

2. *Guidance on the Impact of SAS on AIA Trial Proceedings*, U.S. Patent & Trademark Office (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial ("Office *SAS* Guidance").

Order was to review additional claims and grounds. *See St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375 (Fed. Cir. 2014) ("The statute separates the Director's decision to 'institute' the review, § 314, on one hand, from the Board's 'conduct' of the review 'instituted' by the Director, § 316(c), and the Board's subsequent 'written decision,' § 318, on the other.") The legislative record contains no contemplation of a PTAB procedure whereby, after full PTAB trial and decision and appeal to the Federal Circuit, the PTAB could annul the appeal and remove the entire action and decisions and procedure from history, insulated from review.

The Supreme Court has observed that "the agency bears a 'heavy burden' in attempting to show that Congress 'prohibit [ed] all judicial review' of the agency's compliance with a legislative mandate." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (alteration in original) (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)). In *SAS Institute* the Court reiterated that "nothing in § 314(d) . . . withdraws our power to ensure that an inter partes review proceeds in accordance with the law's demands" and "everything in the statute before us confirms that SAS is entitled to a final written decision addressing all of the claims it has challenged." 138 S. Ct. at 1359. The PTAB's refusal to comply with our Remand Order to implement the Supreme Court's ruling warrants *en banc* attention.

Of further concern is the PTAB's contravention of the purpose of the America Invents Act, to provide agency expertise to resolution of patentability issues. *See* H.R.

Rep. No. 112–98, pt. 1, at 48 (2011) ("[T]he purpose of the [post-grant review proceedings is to] provid[e] quick and cost effective alternatives to litigation."); 157 Cong. Rec. S1352 (daily ed. Mar. 8, 2011) (statement of Sen. Udall) ("These proceedings are intended to serve as a less expensive alternative to courtroom litigation and provide additional access to the expertise of the Patent Office on questions of patentability."). On this background, the PTAB's explanation of agency efficiency and cost is curious, as litigation cost was a primary concern of the America Invents Act.

In the interest of achieving a viable and effective administrative process, and the nation's critical need for an effective system of innovation law and practice, the PTAB's action is seriously flawed. From my colleagues' inaction, I respectfully dissent.

APPENDIX F— REMAND ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (*BioDelivery Sciences Int'l, Inc. v. Aquestive Therapeutics, Inc., et al.*, 17-1265, 17-1266, 17-1268), DATED JULY 31, 2018

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1265, 2017-1266, 2017-1268

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Appellant,

v.

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

Appellee,

ANDREI IANCU, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,

Intervenor.

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

ON MOTION

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

Appendix F

ORDER

BioDelivery Sciences International, Inc. ("BioDelivery") moves to remand this case to the Patent Trial and Appeal Board to consider non-instituted claims and noninstituted grounds in accordance with the Supreme Court's recent decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 200 L. Ed. 2d 695 (2018). Aquestive Therapeutics, Inc. ("Aquestive") and the PTO Director, who has intervened, oppose. Having considered the parties' arguments and our recent decisions interpreting *SAS* and requests based thereon, we *remand*.

DISCUSSION

BioDelivery filed three petitions for *inter partes* review of U.S. Patent No. 8,765,167 ("the '167 Patent"). In IPR2015-00165, BioDelivery challenged a total of 22 claims (1, 4, 6-9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125-127) based upon seven grounds of unpatentability. The PTAB instituted review of 15 claims (1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125-127) based upon less than all asserted grounds. Similarly, in IPR2015-00168 and IPR2015-00169, the PTAB instituted on less than all asserted grounds of unpatentability but did institute on all challenged claims (16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 for IPR2015-00168 and 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110-116, and 124 for IPR2015-00169).

The Patent Trial and Appeal Board ("PTAB") decided each petition separately, and issued separate final written

decisions that sustained the patentability of all instituted claims of the '167 Patent on all instituted grounds, and included discussion concerning the application of collateral estoppel between *inter partes* reexamination and *inter partes* review. BioDelivery appealed the PTAB's three decisions to this court. Aquestive responded, and the Director intervened to confess error as to the PTAB's assumption that *inter partes* reexamination could give rise to collateral estoppel in *inter partes* review.

This court received oral argument in the three appeals on February 9, 2018. On April 24, 2018, the Supreme Court issued its decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 200 L. Ed. 2d 695 (2018), explaining that in establishing *inter partes* review, Congress set forth "a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding." 138 S. Ct. at 1355. The Court held that if the Director institutes review proceedings, the PTAB review must proceed "in accordance with or in conformance to the petition," *id.* at 1356 (internal quotations omitted), 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)). The Court stated: "Nothing suggests the Director enjoys a license to depart from the petition and institute a *different* inter partes review of his own design." *Id.* at 1356 (emphasis in original). Thus the Court emphasized that "the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation," *id.*, and that "the petitioner's contentions, not the Director's discretion, define the scope of the litigation all the way from institution through to conclusion," *id.* at 1357.

Appendix F

Nine days after the Court's *SAS* decision issued, Bio-Delivery requested that this court remand the final decision in IPR2015-00165 to consider the patentability of the non-instituted claims. *See* ECF No. 88. In response, Aquestive argued that BioDelivery had waived any *SAS*-based relief for failing to raise any issue of non-instituted claims during this appeal. *See* ECF No. 90. In addition, Aquestive argued that a remand would not alter the result on appeal. *Id.*

Orders in other cases began to issue from this court, applying the Court's decision in *SAS* and outlining the contours of *SAS*-based requests for relief. *See, e.g., Ulthera, Inc. v. DermaFocus LLC*, No. 2018-1542, 2018 U.S. App. LEXIS 21627, at *4 (Fed. Cir. May 25, 2018) (granting petitioner's motion for remand to the PTAB to consider non-instituted claims); *Polaris Indus. Inc. v. Arctic Cat, Inc.*, 724 F. App'x 948, 949 (Fed. Cir. 2018) (holding that a patent owner "may request a remand to allow the Board to consider noninstituted claims and grounds").

This court explained that *SAS* "require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition." *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018); *see also Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1371 n.1 (Fed. Cir. 2018) ("[T]he statute does not permit a partial institution leading to a partial final written decision."). Post-*SAS* cases have held that it is appropriate to remand to the PTAB to consider non-instituted claims as well as non-instituted grounds. *See, e.g., Adidas AG*

v. Nike, Inc., 894 F.3d 1256, 2018 WL 3213007, at *2 (Fed. Cir. 2018) (remanding for the PTAB to consider a noninstituted ground); *Broad Ocean Techs., LLC v. Nidec Motor Corp.*, 727 Fed. Appx. 686, 2018 WL 2979928, at *1 (Fed. Cir. 2018) (remanding after summary affirmance instructing the PTAB to consider the noninstituted claims); *Nestle Purina PetCare Co. v. Oil-Dri Corp. of Am.*, No. 2017-1744, 2018 U.S. App. LEXIS 15861, at *2-3 (Fed. Cir. June 11, 2018) (remanding to consider non-instituted grounds); *Baker Hughes Oilfield Operations, LLC v. Smith Int'l, Inc.*, Nos. 2018-1754, -1755, 2018 U.S. App. LEXIS 18480, at *4-5 (Fed. Cir. May 30, 2018) (remanding to the PTAB to consider non-instituted claims and non-instituted grounds); *Ulthera*, 2018 U.S. App. LEXIS 21627 at *4 (remanding to the PTAB to consider non-instituted claims). *Cf. PGS Geophysical*, 891 F.3d at 1359-60 ("treat[ing] claims and grounds the same . . . without distinguishing non-instituted claims from non-instituted grounds").

We also declined to find that a party waived its right to seek *SAS*-based relief due to failure to argue against partial institution before the PTAB. *Polaris*, 724 F. App'x at 949-50 (citing *Hormel v. Helvering*, 312 U.S. 552, 558-59, 61 S. Ct. 719, 85 L. Ed. 1037 (1941) (holding an exception to the waiver rule exists in "those [cases] in which there have been judicial interpretations of existing law after decision below and pending appeal—interpretations which if applied might have materially altered the result")); *accord In re Micron Tech., Inc.*, 875 F.3d 1091, 1097 (Fed. Cir. 2017) (acknowledging that "a sufficiently sharp change of law sometimes is a ground for

permitting a party to advance a position that it did not advance earlier in the proceeding when the law at the time was strongly enough against that position"); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (holding that "[g]iven the change in law, it would be unfair at this stage of the case to apply Hilton Davis' statements against it or estop it from augmenting the record to show the reason for the claim amendment based on other facts that may be available").

Both Aquestive and the Director argue that BioDelivery has waived its right to seek *SAS*-based relief for not raising the issue (A) upon the Supreme Court agreeing to hear *SAS* in May 2017, *see* ECF No. 93 at 2; (B) during the pendency of the *inter partes* reviews, *see* ECF No. 92 at 4; or (C) during the briefing period in this appeal, *see id.* As discussed in *Polaris*, however, *SAS* represented a significant change in law that occurred during the pendency of BioDelivery's appeals. *Polaris*, 724 F. App'x at 949 ("Precedent holds that a party does not waive an argument that arises from a significant change in law during the pendency of an appeal.") (collecting cases). Indeed, we remarked that "any attempt to argue against partial institution [prior to *SAS*] would have been futile under the Board's regulations and our precedent." *Id.* at 950. It is clear that waiver does not apply in the present case.

Aquestive and the Director also argue that BioDelivery's motion requesting remand for consideration of noninstituted grounds is untimely. *See* ECF No. 93 at 4 ("Biodelivery Sciences has waited nearly two months after

the *SAS* decision to seek relief—after the parties spent the time to brief and argue the case, and more than three months after the appeal was submitted to the panel for decision."); ECF No. 92 at 6 ("Even if Appellant did not waive its arguments for a complete remand, its argument that the appeals from all three IPRs should be terminated and remanded is untimely.").

Nine days after the *SAS* decision, BioDelivery filed its first request for *SAS*-based relief from the PTAB's institution of less than all claims in IPR2015-00165. *See* ECF No. 88; *see also SAS*, 138 S. Ct. at 1354 ("But instead of instituting review on all of the claims challenged in the petition, the Director instituted review on only some (claims 1 and 3-10) and denied review on the rest."); *id.* at 1359-60 ("Because everything in the statute before us confirms that SAS is entitled to a final written decision addressing all of the claims it has challenged and nothing suggests we lack the power to say so, the judgment of the Federal Circuit is reversed and the case is remanded for further proceedings consistent with this opinion."). Aquestive did not, at that time, complain that this request was untimely, nor could it have reasonably done so.

BioDelivery made its second request for *SAS*-based relief soon after this court began ordering remands when the PTAB considered less than all asserted grounds, explaining that such requests were appropriate in view of *SAS*. *Compare* ECF No. 91 (dated June 19, 2018), *with Polaris*, 724 Fed. Appx. 948 (issued 2018), *Baker Hughes Oilfield Operations, LLC*, 2018 U.S. App. LEXIS 18480 (issued May 30, 2018), *and Nestle Purina PetCare Co.*,

2018 U.S. App. LEXIS 15861 (issued June 11, 2018). Aquestive argues that BioDelivery should have requested this type of relief earlier, pointing to the PTO's informal "guidance" memorandum dated April 26, 2018 as evidence that "in view of *SAS*, [the PTAB] was going to institute on all claims and grounds of unpatentability raised in the petition." ECF No. 92 at 6-7 (discussing *Guidance on the Impact of* SAS *on AIA Trial Proceedings*, U.S. Patent & Trademark Office (Apr. 26, 2018), *available at* https://www.uspto.gov/patentsapplication-process/patent-trial-and-appeal-board/trials/ guidance-impact-sas-aia-trial). The PTO's salutary decision concerning future action does not insulate earlier PTAB actions from remedy.

Aquestive further argues that because the PTAB recognized *SAS* to require institution on all challenged claims and all challenged grounds, BioDelivery should have also recognized this and requested complete relief in its May 3 filing. ECF No. 92 at 7 (discussing this court's statements in *PGS Geophysical*). We agree that *SAS* requires institution on all challenged claims and all challenged grounds. *See PGS Geophysical*, 891 F.3d at 1360 ("Equal treatment of claims and grounds for institution purposes has pervasive support in SAS."). However, even if a prior action did not appear unlawful at the time, this does not insulate it from corrective action. The second request for *SAS*-based relief was not untimely simply because BioDelivery did not predict that this court would authorize requests for remand when the PTAB instituted on less than all grounds as well as on all claims. It is undisputed that BioDelivery acted promptly after these occurrences, requesting remand within days of

this court's first orders granting remand for the PTAB's failure to institute on all asserted grounds.

Aquestive also asks that if this court decides that remand is appropriate, that we first decide the presently appealed issues. However, "[a]ppellate courts have historically disfavored piecemeal litigation and permitted appeals from complete and final judgments only." *W.L. Gore & Assocs., Inc. v. Int'l Med. Prosthetics Research Assocs., Inc.*, 975 F.2d 858, 861 (Fed. Cir. 1992) (citing *Catlin v. United States*, 324 U.S. 229, 65 S. Ct. 631, 89 L. Ed. 911 (1945)). The inadequacy of the three PTAB decisions, as established by *SAS*, weighs against deciding these appeals of fewer than the required issues. This is precisely the type of piecemeal litigation that is historically disfavored.

Aquestive also asserts that remand would result in prejudice "because it will negatively impact Appellee's ability to assert and defend its patent rights in other venues and against other parties." ECF No. 92 at 14. Aquestive states that it "is actively enforcing its patents in numerous district court litigations," *id.*, including two district court actions against BioDelivery. We take note that one of these suits was stayed (jointly) during the *inter partes* reviews. *See Reckitt Benckiser Pharm., Inc. v. BioDelivery Sci. Int'l, Inc.*, No. 5:15-cv-00350-D (E.D.N.C. Sept. 22, 2014), ECF Nos. 39 & 42. Whether district court litigation is stayed for these remand procedures is within the province of the district court. Thus, the prejudice alleged by Aquestive does not weigh against a remand in this case.

Accordingly,

IT IS ORDERED THAT:

(1) Biodelivery's request for remand to implement the Court's decision in *SAS* is granted in Federal Circuit Appeal Nos. 2017-1265, 2017-1266, and 2017-1268.

(2) The PTAB's decisions in PTAB Nos. IPR2015-00165, IPR2015-00168, and IPR2015-00169, are vacated.

(3) Pursuant to Federal Circuit Rule 41, this order shall constitute the mandate in Appeal Nos. 2017-1265, 2017-1266, and 2017-1268.

(4) Each party shall bear its costs.

July 31, 2018
Date

FOR THE COURT

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

APPENDIX G — MOTION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (*BioDelivery Sciences Int'l, Inc. v. Aquestive Therapeutics, Inc., et al.*, 17-1265, 17-1266, 17-1268), DATED JUNE 19, 2018

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPEAL NOS. 17-1265, 17-1266, 17-1268

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Appellant,

v.

AQUESTIVE THERAPEUTICS, INC.,

Appellee,

and

ANDREI IANCU, DIRECTOR, U.S. PATENT
AND TRADEMARK OFFICE,

Intervenor.

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

APPELLANT BIODELIVERY SCIENCES INTERNATIONAL, INC.'S MOTION TO TERMINATE APPEAL AND REMAND IN VIEW OF *SAS INSTITUTE V. IANCU; POLARIS INDUS. INC. V. ARTIC CAT, INC.;* AND *PGS GEOPHYSICAL V. IANCU*

Appendix G

[TABLES INTENTIONALLY OMITTED]

REQUESTED RELIEF

Appellant BioDelivery Sciences International, Inc. respectfully moves for termination of this appeal and remand to the Patent Trial and Appeal Board for further consideration. In each of the three *inter partes* review decisions on appeal, the Board failed to address all of challenges that BioDelivery presented in the corresponding petition. In fact, although BioDelivery challenged the patent on 17 grounds in the relevant petitions, the Board only instituted review based upon three of those 17 challenges.

In *SAS Institute, Inc. v. Iancu*, the Supreme Court held that 35 U.S.C. § 318(a) requires the final written decision in an *inter partes* review to address every claim the petitioner has challenged. *See* 138 S. Ct. 1348, 1354 (April 24, 2018). In *Polaris Indus. Inc. v. Arctic Cat, Inc.,* this Court held that a party *may* seek remand when the final written decision does not comply with the requirements of 35 U.S.C. § 318(a). *See* No. 2017-1870, 2018 WL 2435544, at *1 (Fed. Cir. May 30, 2018) (per curiam). In *PGS Geophysical AS v. Iancu,* this Court found that 35 U.S.C. § 318(a) requires the final written decision in an *inter partes* review to address not just every challenged claim, but also every patentability challenge in the petition. *See* No. 2016-2470, 2018 WL 2727663, at *3 (Fed. Cir. June 7, 2018). In *PGS,* this Court also noted that the requirements of 35 U.S.C. § 318(a) as to a final written decision with a pending appeal will be waived without an appropriate request for remand. *See id.*

It is clear in view of *PGS* that, by issuing each of the decisions in this appeal without addressing all of the challenges in any of the relevant petitions, the Board exceeding its statutory authority under 35 U.S.C. § 318(a). BioDelivery seeks to gain the full benefit of the requirements of 35 U.S.C. § 318(a). Accordingly, BioDelivery respectfully requests that this Court terminate this appeal and remand the three *inter partes* review proceedings to the Board for consideration of all of the challenges in the relevant petitions.

PROCEDURAL HISTORY

This consolidated appeal addresses Board decisions in three *inter partes* review proceedings: IPR2015-00165, IPR2015-00168, and IPR2015-00169. In its petition for each proceeding, Appellant BioDelivery challenged certain claims of US Patent No. 8,765,167 on a plurality of grounds. In each *inter partes* review proceeding, the Board instituted review based on only one of the plurality of petition challenges. The Board issued a "final written decision" in each of the three proceedings, which decisions are the subject of this appeal.

In IPR2015-00165, BioDelivery challenged a total of 22 claims (1, 4, 6-9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, 125-127) based upon seven grounds of unpatentability. Appx585. The grounds included both anticipation and obviousness grounds, and involved four references, alone or in combinations. Appx585. The Board instituted review of only 15 claims (1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, 125-127) based upon one ground—anticipation by the

Chen reference. Appx642 (Ex. D at 16).[1] The Board denied institution of an *inter partes* review as to any of the other challenged claims or claim challenges. Appx657 (Ex. D at 31). In the final written decision, the Board found that "Petitioner has not shown . . . that the film compositions described in Chen inherently meet the requirement in claim 1 of a substantially uniform distribution of the active component." Appx013 (Ex. A at 13). The Board denied BioDelivery's requested rehearing on September 26, 2016. Appx102.

In IPR2015-00168, BioDelivery challenged a total of 12 claims based upon five grounds of unpatentability. Appx660-661; Appx729 (Ex. E at 5). The grounds included both anticipation and obviousness challenges, and involved three references, alone or in combinations. *Id.* The Board instituted review of all of the challenged claims based upon one ground—obviousness over Chen in view of Tapolsky. Appx742 (Ex. E at 18). The Board denied institution of an *inter partes* review as to all of the other claim challenges. Appx743 (Ex. E at 19). In the final written decision, the Board found "Petitioner has not shown . . . that the asserted prior art teaches a film with substantially

1. Pursuant to Fed. R. App. P. 27(a)(2)(B), BioDelivery attaches the decisions at issue as exhibits. The decisions are attached with the following identifiers: Ex. A, Final Written Decision in IPR2015-00165; Ex. B, Final Written Decision in IPR2015-00168; Ex. C, Final Written Decision in IPR2015-00169; Ex. D, Institution Decision in IPR2015-00165; Ex. E, Institution Decision in IPR2015-00168; Ex. F, Institution Decision in IPR2015-00169. Parallel citations to the decisions, where they are included in the Appendix and where they are attached as exhibits, are provided using the format: Appx ___ (Ex. ___ at ___).

uniform distribution of the active component." Appx041 (Ex. B at 9). The Board denied BioDelivery's requested rehearing on September 26, 2016. Appx117.

In IPR2015-00169, BioDelivery challenged a total of 22 claims based upon five grounds of unpatentability. Appx746-747; Appx815 (Ex. F at 3). The grounds included both anticipation and obviousness challenges over a total of three references. *Id.* The Board instituted review of all of the challenged claims based upon only one ground—obviousness over Chen in view of Tapolsky. Appx835 (Ex. F at 23). The Board denied institution of an *inter partes* review as to all of the other claim challenges. Appx836 (Ex. F at 24). In the final written decision, the Board found "Petitioner has not shown that Chen and Tapolsky describe, or render obvious, film compositions that have a substantially uniform distribution of the active component" (Appx099 (Ex. C at 37)), in part because "Petitioner has not shown that Chen's disclosure . . . is an inherent disclosure of a film with a substantially uniform distribution of the active component." Appx089 (Ex. C at 27); *see also* Appx092 (Ex. C at 30). The Board denied BioDelivery's requested rehearing on September 26, 2016. Appx130.

BioDelivery appealed to this Court following the denial of its rehearing requests in each proceeding. Oral arguments in this case had been heard when the Supreme Court issued its *SAS* opinion.

Shortly after the Supreme Court issued its *SAS* opinion, on May 3, 2018, BioDelivery submitted a notice

of supplemental authority pointing out that at least one of the decisions at issue in the consolidated should be remanded because it does not satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS*, or qualify as a final written decision. At the Court's invitation, on May 17, 2018, Appellee Aquestive Therapeutics, Inc. filed a responsive notice of supplemental authority opposing remand.

ARGUMENT

I. The Statute Requires the Final Written Decision in an *Inter Partes* Review to Address All of the Petition's Patentability Challenges.

In *SAS Institute, Inc. v. Iancu,* the Supreme Court held that, "when [35 U.S.C.] § 318(a) says the Board's final written decision 'shall' resolve the patentability of 'any patent claim challenged by the petitioner,' it means the Board *must* address *every* claim the petitioner has challenged." 138 S. Ct. 1348, 1354 (April 24, 2018) (emphasis original). Thus, *SAS* established that 35 U.S.C. § 318(a) requires a final written decision to address all of the claims challenged in the relevant petition. But *SAS* left undecided the question of whether 35 U.S.C. § 318(a) requires a final written decision to address all of the patentability challenges in the relevant petition.

Less than two week ago, in *PGS Geophysical AS v. Iancu,* this Court decided that question. This Court explained that it "read ... the *SAS* opinion as interpreting the statute to require a simple yes-or-no institution choice

respecting a petition, *embracing all challenges included in the petition,* and [it has] seen no basis for a contrary understanding of the statute in light of *SAS*." *PGS,* 2018 WL 2727663, at *4 (Fed. Cir. June 7, 2018) (emphasis added). Thus, this Court decreed that it "will treat claims and grounds the same in considering the *SAS* issues currently before [it]." *Id.* at *3. In other words, this Court has now established that 35 U.S.C. § 318(a) requires a final written decision to address all of the patentability challenges in the relevant petition.

In each of the three decisions at issue in this appeal, the Board decided only one of a plurality of patentability challenges presented in the relevant petition. Accordingly, each of the decisions at issue in this appeal does not comply with 35 U.S.C. § 318(a) in view of *PGS*. Stated another way, *PGS* establishes that the Board exceeded its statutory authority under 35 U.S.C. § 318(a) in issuing each of the three decisions at issue in this appeal.

II. Remand To the Board Is Appropriate In View of the Intervening Change in Law as to the Requirements of 35 U.S.C. Section 318(a).

In *Polaris Indus. Inc. v. Arctic Cat, Inc.,* this Court held that *SAS* constitutes an intervening change of law. *See* 2018 WL 2435544, at *1 (Fed. Cir. May 30, 2018) (per curiam). Before the Supreme Court's *SAS* decision, 35 U.S.C. § 318(a) was not interpreted to require a final written decision to address all of the claims challenged in the relevant petition. Accordingly, the Board changed its practice in view of the Supreme Court's *SAS* decision.

Compare 37 C.F.R. § 42.108(a) (added Sept. 26, 2012) ("When instituting inter partes review, the Board may authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim.") *with* Guidance on the Impact of SAS on AIA Trial Proceedings, <https://www.uspto.gov/patentsapplication- process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aiatrial> (April 26, 2018) ("As required by the [the Supreme Court's *SAS*] decision, the [Board] will institute as to all claims or none.").

In *Polaris,* this Court further held that "Polaris did not waive its right to seek remand by not arguing against partial institution before the Board." *Polaris,* 2018 WL 2435544, at *1. It explained that "[p]recedent holds that a party does not waive an argument that arises from a significant change in law during the pendency of an appeal." *Id.* at *1 (citing *Hormel v. Helvering,* 312 U.S. 552, 558–59 (1941)). "[A]ny attempt to argue against partial institution would have been futile under the Board's regulations and [this Court's] precedent." *Id.* "[A] litigant [need not] engage in futile gestures merely to avoid a claim of waiver." *In re Micron Tech., Inc.,* 875 F.3d 1091, 1098 (Fed. Cir. 2017) (quoting *Chassen v. Fid. Nat'l Fin., Inc.,* 836 F.3d 291, 293 (3d Cir. 2016)).

After full briefing in *Polaris*, the Court remanded two *inter partes* reviews for further consideration per curiam. *See Polaris,* 2018 WL 2435544, at *1. The Court held that remand is warranted when sought by a party to the appeal because "the Board's existing final written decisions do not

address all challenged claims or all grounds." *Id.*; *see also* Ex. G, *Nestle Purina PetCare Co. v. Oil-Dri Corp. of Am.*, No. 2017-1744, Slip Op. at 3-4 (Fed. Cir. June 11, 2018) (per curiam) (remanding an appeal of an *inter partes* review for further consideration by the Board where one party moved for remand and the final written decision did not address all of the patentability challenges in the petition); *Broad Ocean Technologies, LLC v. Nidec Motor Corp.*, No. 2017-1933, 2018 WL 2979928, at *1 (Fed. Cir. June 14, 2018) (on petition for rehearing following affirmance of Board decision upholding instituted claims, remanding to Board for decision on non-instituted claims). Remand is appropriate to permit full development of the factual record. *See Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (remanding to the district court in view of a change in law to permit further fact finding).

Like the Supreme Court's *SAS* decision, this Court's *PGS* decision constitutes an intervening change of law. Before this Court's *PGS* decision, 35 U.S.C. § 318(a) was not interpreted to *require* a final written decision to address all of the patentability challenges in the relevant petition. The Patent Office recognized the uncertainty that remained in view of the Supreme Court's *SAS* decision. *See* Guidance on the Impact of SAS on AIA Trial Proceedings, <https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial> (April 26, 2018) ("*At this time,* if the [Board] instates a trial, the [Board] will institute on all challenges raised in the petition.") (emphasis added); *see also* Matthew Johnson, "USPTO Holds Webinar to Discuss Supreme

Court's SAS Decision," <http://www.ptablitigationblog.com/uspto-holds-webinar-to-discuss-supreme-courts-sas-decision/> (May 4, 2018) ("Chief Judge Ruschke explained during the webinar that the [Board] will now institute on all claims challenged or none of them. Further, although not required by SAS, if the [Board] institutes a trial, it will institute on all challenges—meaning all claims and all grounds of unpatentability—raised in the petition."). This Court's *PGS* decision, issued on June 7, 2018, established for the first time that 35 U.S.C. § 318(a) *requires* a final written decision to address all of the patentability challenges in the relevant petition.

Although it did not argue against partial institution before the Board, like Polaris, BioDelivery is free to seek remand in view of the intervening change of law during the pendency of this appeal. Before *SAS* and *PGS*, it would have been futile for BioDelivery to argue to the Board that 35 U.S.C. § 318(a) requires a final written decision to address all of the patentability challenges in the relevant petition. BioDelivery need not engage in futile gestures to avoid a claim of waiver. By not arguing the issue to the Board, BioDelivery did not waive an argument that arises from *SAS* and *PGS's* significant change in law during the pendency of this appeal.

Like Polaris, BioDelivery has not had the benefit of Board decisions that satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*. Despite institution of three *inter partes* review proceedings, BioDelivery only obtained a Board decision on three of the seventeen patentability challenges it presented.

Thus, BioDelivery is free to seek remand in view of the significant intervening change of law during the pendency of this appeal.

III. The Board's Consideration of Only One of the Plurality of Challenges Presented in Each Petition Denies BioDelivery the Full Benefit of 35 U.S.C. 318(a), and Otherwise Prejudices BioDelivery.

BioDelivery expressly seeks the benefit of decisions that satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*. BioDelivery moves for remand of the underlying *inter partes* reviews to the Board for further consideration in view of *SAS* and *PGS*. BioDelivery will be prejudiced if this appeal is not terminated because the decisions at issue here do not comply with the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*,[2] and BioDelivery is subject to the risk of estoppel.

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2. *PGS* also contradicts the decisions on appeal as to finality. In the IPR2015-00165 decision, the Board found that its own '337 decision was not final "because the time for appeal ha[d] not expired." Appx017 (Ex. A at 17)*; see also* Appx046 (Ex. B at 14); Appx082 (Ex. C at 20) (both also concluding that the '337 was not final because the time for appeal had not expired). But *PGS* explained that "agency action is final when the agency's decision-making process is complete and the action determines legal 'rights or obligations' or otherwise gives rise to 'legal consequences.'" *PGS*, 2018 WL 2727663, at *4. The decisions on appeal should have deemed the '337 decision final, under *PGS,* because the Board's decision-making process was complete as to the '337 decision at the time and the '337 decision gave rise to legal consequences.

By issuing the decisions at issue here, the Board acted in excess of its statutory authority and with prejudice to BioDelivery. Despite the Board's institution of three *inter partes* reviews in response to BioDelivery's three petitions, the Board issued no decision that satisfies the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*. In other words, despite its efforts, BioDelivery did not obtain the full benefit of any instituted *inter partes* review. As Judge Newman has observed, "[f]inal determination of the validity of a challenged patent is not achieved when the PTO selects, at its sole and unreviewable choice, which claims it will review and which it will not touch." *SAS Inst., Inc. v. ComplementSoft, LLC.*, 825 F.3d 1341, 1354 (Fed. Cir. 2016) (Newman, J. concurring in part and dissenting in part).

For example, BioDelivery's IPR2015-00165 petition presented anticipation and obviousness challenges. But the Board only instituted *inter partes* review on the question of whether certain challenged claims were anticipated. Appx657 (Ex. D at 31). The Board suggested that *inter partes* review based on other challenges presented in BioDelivery's petition was unnecessary. The Board explained that, "because . . . Petitioner reasonably establishes, based on the record before us, that Chen discloses the controlled drying process recited in the claims, we decline to institute trial as to this ground [*i.e.*, obviousness over Chen, Leung, and Modern Coating]." Appx648 (Ex. D at 22). Thus, in IPR2015-00165, the Board declined to institute review on other presented challenges because BioDelivery was likely to succeed in its anticipation challenge to the claims.

Nonetheless, in the appealed IPR2015-00165 decision, the Board found that "Petitioner has not shown . . . that the film compositions described in Chen inherently meet the requirement in claim 1 of a substantially uniform distribution of the active component." Appx013 (Ex. A at 13). Thus, the Board only decided that certain challenged claims are not anticipated. Although BioDelivery's petition presented anticipation and obviousness challenges, the appealed IPR2015-00165 decision does not decide whether the challenged claims are obvious. Despite the appealed IPR2015-00165 decision, the question of whether the combination of Chen, Leung, and Modern Coating renders the challenged claims obvious remains undecided.

Indeed, the Board has not decided all of the challenges presented in any of BioDelivery's relevant petitions. As *SAS* and *PGS* have since made clear, the Board acted outside of its statutory authority by terminating the underlying *inter partes* reviews without deciding all of the challenges BioDelivery presented in its petitions. For example, the Board has not decided whether the combination of Chen, Leung, and Modern Coating renders claims challenged on that basis obvious. The Board's decision-making process should not be considered complete in view of *SAS* and *PGS*. The decisions on appeal here should not give rise to legal consequences. And the decisions here should not be considered final.

BioDelivery is prejudiced by the possibility that it may be subject to statutory estoppel despite the fact that the decisions are neither final nor complete. After a final written decision, section 315(e) provides that statutory

estoppel applies to any ground that the petitioner raised or reasonably could have raised. *See* 35 U.S.C. § 315(e). But before a final written decision, by the plain language of section 315(e), no statutory estoppel attaches. As *SAS* and *PGS* importantly explain, section 318(a) *requires* a final written decision to address all of the challenged claims and all of the patentability challenges in the relevant petition. Thus, under the statutory scheme of the America Invents Act, as interpreted by *SAS* and *PGS*, a petitioner is not subject to statutory estoppel before all of the challenges presented in its petition have been decided. Accordingly, BioDelivery should not be subject to estoppel under 35 U.S.C. § 315(e) before all of the challenges presented in its petitions have been decided.

But under current precedent, BioDelivery cannot be confident of avoiding statutory estoppel unless the decisions at issue in this appeal are vacated and remanded for further consideration. Some courts have found that statutory estoppel only applies to grounds that were actually decided in the final written decision. *See Intellectual Ventures I LLC v. Toshiba Corp.,* 221 F. Supp. 3d 534, 554 (D. Del. 2016) (finding no estoppel for grounds that were not instituted or petitioned); *Verinata Health, Inc. v. Ariosa Diagnostics, Inc.,* No. 12-05501, 2017 WL 235048, at *3 (N.D. Cal. Jan. 19, 2017) (finding estoppel derived from instituted grounds). Alternatively, some courts have found that statutory estoppel applies to all of the challenges presented in the relevant petition. *See Biscotti Inc. v. Microsoft Corp.,* No. 2:13-01015, 2017 WL 2526231, at *7 (E.D. Tex. May 11, 2017) (recommending application of estoppel to "grounds included in a petition

but determined by the [Board] to not establish a reasonable likelihood of unpatentability"); *see also Milwaukee Elec. Tool Corp. v. Snap-On Inc.*, 271 F. Supp. 3d 990, 1030 (E.D. Wis. 2017) (holding estoppel does not apply to non-instituted grounds, but that "any subset or alternative combination of the instituted references is barred"). It remains unclear how courts will apply statutory estoppel under 35 U.S.C. § 315(e) with respect to Board decisions that do not satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*.

It would be unfair, and contrary to the current statutory scheme, to subject a petitioner to estoppel under 35 U.S.C. § 315(e) without a final written decision that satisfies the requirements of 35 U.S.C. § 318(a)—particularly when the petitioner expressly requested a final written decision that satisfies the requirements of 35 U.S.C. § 318(a) as interpreted by *SAS* and *PGS*. None of the decisions at issue in this appeal satisfy the requirements of 35 U.S.C. § 318(a), as interpreted by *SAS* and *PGS*. Section 315(e) should not bar BioDelivery from raising challenges to the patentability of the claims that were presented in its relevant petitions, but denied a hearing by the Board. Before any statutory estoppel may attach, BioDelivery expressly requests the benefit of Board decisions that address all of the challenges BioDelivery presented in its relevant petitions.

Appendix G

CONCLUSION

For the foregoing reasons, BioDelivery respectfully requests that this Court terminate this consolidated appeal and remand the three *inter partes* reviews for further proceedings before the Board consistent with *SAS* and *PGS*.

Appendix G

STATEMENT REGARDING CONSENT OR OPPOSITION

BioDelivery asked Aquestive and the U.S. Patent and Trademark Office if they would oppose a motion to terminate this appeal and remand on Monday, June 18, 2018. Aquestive and the U.S. Patent and Trademark Office each informed BioDelivery that it will oppose this motion on the basis of timeliness on Tuesday, June 19, 2018.

Dated: June 19, 2018

Respectfully submitted,

/s/ Kia L. Freeman

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Attorneys for Appellant

Appendix G

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief of the Appellant complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) and contains 4,023 words, as determined by the word-count function of Microsoft Word, excluding the portions of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

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 2010 in 14-point Times New Roman font.

Dated: June 19, 2018

Respectfully submitted,

/s/ Kia L. Freeman
Kia L. Freeman

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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:

   Not applicable.

/s/ Kia L. Freeman
Kia L. Freeman

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CERTIFICATE OF SERVICE

I hereby certify that on June 19, 2018, 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