

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

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Appellant

v.

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

2019-1643, 2019-1644, 2019-1645

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

ON MOTION

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MA, for appellant. Also represented by THOMAS F. FOLEY,
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San Francisco, CA; KATHERINE DOROTHY CAPPAERT, Wash-
ington, DC.

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

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

Opinion dissenting filed by *Circuit Judge* NEWMAN.

REYNA, *Circuit Judge*.

ORDER

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

BACKGROUND

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION

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

[t]he Director¹ may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

35 U.S.C. § 314(a) (footnote added). Subsection (a) identifies a threshold requirement that must be met before the Director is even authorized to institute review, and then “grants the Director discretion not to institute even when the threshold is met.” *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018) (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016)). In other words, the Director is limited in his power to institute review but has discretion to not institute review even when the threshold showing is met. *See Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (“While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons such as administrative efficiency”), *cert. denied*, 139 S. Ct. 1547 (2019).

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

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

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

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

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

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

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

provision—§ 314(d). “[W]here a patent holder merely challenges the Patent Office’s ‘determin[ation] that the information presented in the petition . . . shows that there is a reasonable likelihood’ of success ‘with respect to at least 1 of the claims challenged,’ . . . § 314(d) bars judicial review.” *Cuozzo*, 136 S. Ct. at 2142.

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

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

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

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

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

Here, the Board's orders on remand modifying its previous institution decisions constitute the Board's (1) determination of whether the information presented in the petitions shows that there is a reasonable likelihood of success with respect to at least 1 of the claims challenged, and (2) exercise of its discretion whether to institute IPR. Section 314(d) bars judicial review of both aspects of the Board's decisions. *Cuozzo*, 136 S. Ct. at 2142.

Accordingly,

IT IS ORDERED THAT:

The above-captioned appeals are dismissed.

FOR THE COURT

August 29, 2019
Date

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

ISSUED AS A MANDATE: August 29, 2019

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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 (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 (D.C. Cir. 1977) (“The decision of a federal appellate court establishes the law binding further action in the litigation by another body subject to its authority. . . . These principles, so familiar in operation within the hierarchy of judicial benches, indulge no exception for reviews of administrative agencies.”); *see also In re Sanford Fork & Tool Co.*, 160 U.S. 247, 255 (1895) (“When a case has been once decided by this court on appeal, and remanded to the circuit court, whatever was before this court, and disposed of by its decree, is considered as finally settled. The circuit court is bound by the decree as the law of the case, and must carry it into execution according to the mandate. That court cannot vary it, or examine it for any other purpose than execution. . . .”).

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

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

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

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

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

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

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

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

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

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.