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 PETITION FOR REHEARING EN BANC

KIA LYNN FREEMAN, McCarter & English, LLP, Boston, MA, filed a petition for rehearing en banc for appellant. Also represented by THOMAS F. FOLEY, WYLEY SAYRE PROCTOR.

JOHN LLOYD ABRAMIC, Steptoe & Johnson, LLP, Chicago, IL, filed a response to the petition for appellee. Also represented by JAMIE LUCIA, San Francisco, CA; KATHERINE DOROTHY CAPPAERT, Washington, DC.

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.

O R D E R

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

[*] Circuit Judge Stoll did not participate.

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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

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[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.

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 *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.

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[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").

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 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.