

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

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**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*

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2017-1265, 2017-1266, 2017-1268

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

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**ON MOTION**

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LEE CARL BROMBERG, McCarter & English, LLP, Bos-  
ton, MA, argued for appellant. Also represented by ERIK  
PAUL BELT, KIA LYNN FREEMAN, WYLEY SAYRE PROCTOR,  
DEBORAH M. VERNON; DANIELLE L. HERRITT, Womble  
Bond Dickinson (US) LLP, Boston, MA; CORA RENAE

HOLT, HOWARD WARREN LEVINE, THOMAS JOHN SULLIVAN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC; CHARLES E. LIPSEY, Reston, VA; JENNIFER SWAN, Palo Alto, CA.

JOHN LLOYD ABRAMIC, Steptoe & Johnson, LLP, Chicago, IL, argued for appellee. Also represented by CASSANDRA ADAMS, New York, NY; HAROLD FOX, JAMES FRANCIS HIBEY, GRETCHEN P. MILLER, Washington, DC; JAMIE LUCIA, San Francisco, CA.

MOLLY R. SILFEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by THOMAS W. KRAUSE, BENJAMIN T. HICKMAN.

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

NEWMAN, *Circuit Judge*.

## ORDER

BioDelivery Sciences International, Inc. (“BioDelivery”) moves to remand this case to the Patent Trial and Appeal Board to consider non-instituted claims and non-instituted grounds in accordance with the Supreme Court’s recent decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (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 (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.

Nine days after the Court’s *SAS* decision issued, BioDelivery 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, slip op. at 3 (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.*, No. 2018-1180, 2018 WL 3213007, at \*2 (Fed. Cir. July 2,

2018) (remanding for the PTAB to consider a non-instituted ground); *Broad Ocean Techs., LLC v. Nidec Motor Corp.*, No. 2017-1933, 2018 WL 2979928, at \*1 (Fed. Cir. June 14, 2018) (remanding after summary affirmance instructing the PTAB to consider the non-instituted claims); *Nestle Purina PetCare Co. v. Oil-Dri Corp. of Am.*, No. 2017-1744, slip op. at 3–4 (Fed. Cir. June 11, 2018) (remanding to consider non-instituted grounds); *Baker Hughes Oilfield v. Smith Int’l, Inc.*, Nos. 2018-1754, -1755, slip op. at 4–5 (Fed. Cir. May 30, 2018) (remanding to the PTAB to consider non-instituted claims and non-instituted grounds); *Ulthera*, slip op. at 3 (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 (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 non-instituted 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* (issued May 30, 2018), *Baker Hughes Oilfield* (issued May 30, 2018), and *Nestle Purina PetCare* (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/patents-application-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 (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) Bidelivery'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.

FOR THE COURT

July 31, 2018  
Date

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