

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

MONOSOL RX, LLC,¹
Patent Owner.

Cases IPR2015-00165,
IPR2015-00168, and IPR2015-00169
Patent 8,765,167 B2²

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

Per Curiam.

ORDER
Conduct of the Proceeding
37 C.F.R. § 42.5

¹ The caption of the Order remanding these proceedings to the Board identifies “AQUESTIVE THERAPEUTICS, INC., fka MonoSol Rx, LLC” as the Patent Owner. *BioDelivery Scis. Int’l. v. Aquestive Therapeutics, Inc.*, 2018 WL 3625151 (Fed. Cir. 2018). The parties are reminded of their obligation to maintain up-to-date Mandatory Notices. *See* 37 C.F.R. § 42.8.

² This order addresses issues involving all of the identified cases. We exercise our discretion to issue one order to be filed in each case. The parties are authorized to use this style heading when filing a single paper in all three proceedings, provided that such heading includes a footnote attesting that “the word-for-word identical paper is filed in each proceeding identified in the heading.”

IPR2015-00165, IPR2015-00168, and IPR2015-00169
Patent 8,765,167 B2

In response to requests by BioDelivery Sciences International, Inc. (“Petitioner”), the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) has remanded Petitioner’s appeals of this Board’s final decisions in each of IPR2015-00165, IPR2015-00168, and IPR2015-00169 to “implement the [Supreme] Court’s decision in *SAS [Institute Inc. v. Iancu]*, 138 S. Ct. 1348 (2018).” *BioDelivery Scis. Int’l. v. Aquestive Therapeutics, Inc.*, 2018 WL 3625151 at *4 (Fed. Cir. 2018).

In its Order, the Federal Circuit stated that the Board’s “decisions in PTAB Nos. IPR2015-00165, IPR2015-00168, and IPR2015-00169, are vacated.” *Id.*

In *SAS*, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute a review proceeding on fewer than all claims challenged. *SAS*, 138 S. Ct. at 1354. The Federal Circuit directs that, if the Director institutes a proceeding, “*SAS* requires institution on all challenged claims and all challenged grounds.” *BioDelivery v. Aquestive*, 2018 WL 3625151 at *3 (citing *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (“Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*.”)).

Pursuant to the Federal Circuit’s Order to implement the Supreme Court’s decision in *SAS*, we direct the parties to submit briefing addressing specifically whether an appropriate course of action going forward would be to vacate our prior institution decisions in these proceedings and deny the petitions in their entireties at this time.

The parties are reminded that, at the original institution stage of these proceedings, a significant majority of the grounds presented by Petitioner

IPR2015-00165, IPR2015-00168, and IPR2015-00169
Patent 8,765,167 B2

were determined on the merits not to meet the standard for institution of trial. *See* IPR2015-00165, Paper 6, 10–31 (instituting as to one of seven grounds of unpatentability; four of seven grounds determined not to meet institution standard on the merits; two other grounds denied because presented on contingent basis); IPR2015-00168, Paper 6, 9–18 (instituting as to one of five grounds; four of five grounds determined not to meet institution standard on the merits); IPR2015-00169, Paper 6, 10–23 (instituting as to one of five grounds; four of five grounds determined not to meet institution standard on the merits). In addition, in relation to each instituted ground in each case, as addressed in our final written decisions in the three IPRs at issue, we determined that Petitioner had not shown by a preponderance of the evidence that any challenged claim of the '167 patent was unpatentable.

Because we previously denied institution as to a significant majority of grounds presented by Petitioner, and because we “sustained the patentability of all instituted claims of the '167 Patent on all instituted grounds” in our final written decisions, we direct the parties to submit briefing addressing specifically whether an appropriate course of action would be to vacate our prior institution decisions and deny the petitions now, in view of the Federal Circuit’s recent decision to vacate and remand our final written decisions “to implement the Court’s decision in *SAS*.” *BioDelivery Scis.*, 2018 WL 3625151 at *1, *4.

The parties’ briefing regarding the propriety of denying institution shall be no more than ten (10) pages long, and shall be submitted no later than September 10, 2018.

IPR2015-00165, IPR2015-00168, and IPR2015-00169
Patent 8,765,167 B2

In consideration of the foregoing, it is hereby:

ORDERED that by September 10, 2018, the parties shall, either jointly or separately, in accordance with the directions above, submit briefing that addresses specifically whether denying institution is the appropriate course of action at this stage in all three proceedings, in view of the Federal Circuit's decision to vacate and remand our final written decisions in view of *SAS*.

IPR2015-00165, IPR2015-00168, and IPR2015-00169
Patent 8,765,167 B2

PETITIONER:

Dannielle L. Herritt
Deborah M. Vernon
Kia L. Freeman
MCCARTER & ENGLISH, LLP
djerrott@mccarter.com
devernon@mccarter.com
kfreeman@mccarter.com

PATENT OWNER:

Daniel A. Scola Jr.
Michael I. Chakansky
HOFFMANN & BARON, LLP
dscola@hbiplaw.com
mchakansky@hbiplaw.com
165ipr@hbiplaw.com