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November 7, 2019

VIA CM/ECF

Peter R. Marksteiner
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 20439

Re: ***BioDelivery Sciences International, Inc. v. Aquestive Therapeutics, Inc.***
Nos. 2019-1643, -1644, -1645

Dear Mr. Marksteiner:

Pursuant to Federal Rule of Appellate Procedure 28(j), Appellee Aquestive Therapeutics, Inc. ("Aquestive") responds to the November 5, 2019 letter by Appellant BioDelivery Sciences International, Inc. ("BDSI") invoking *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 2018-2140 (Fed. Cir. Oct. 31, 2019) ("*Arthrex*").

Despite BDSI's attempt to shoehorn *Arthrex* into this appeal, that decision has no relevance here. The only question here is whether the Board correctly followed *SAS* on remand by deciding to deny institution of *Inter Partes* Review. *Arthrex* is of no moment in answering that question and concerns only the constitutionality of a Board panel issuing a final written decision. The *Arthrex* Court's decision to "partially invalidate statutory removal protections" for APJs was a narrowly tailored outcome based on its analysis of the Appointments Clause. *Arthrex*, Slip op. at 26. The *Arthrex* Court explicitly stated that the "impact of this case [is] limited to those cases where final written decisions were issued and where litigants present an Appointments Clause challenge on appeal." Slip. op. at 29. Neither circumstance applies here. This is an appeal of decisions denying institution, not a final written decision. Moreover, BDSI has never raised or suggested that the Appointments Clause could form the basis for any of its challenges to the Board's actions in this appeal. Thus, *Arthrex* is not applicable.

Notably, the logical conclusion of BDSI's untimely argument concerning *Arthrex* is that BDSI must be asking this Court to remand ***all*** appeals from ***any*** Board decision. Although BDSI does not explicitly ask for that result, the implicit request is clear from its last-ditch effort to invoke the Court's narrowly-tailored resolution of an appeal based on an Appointments Clause

challenge. *See Customedia Techs., LLC v. Dish Network*, No. 2019-1001 (Fed. Cir. Nov. 4, 2019) (denying motion to vacate and remand because appellant "did not raise any semblance of an Appointments Clause challenge in its opening brief or raise this challenge in a motion filed prior to its opening brief").

Accordingly, *Arthrex* does not change the result here; and there is no need for further consideration of BDSI's appeal.

Respectfully submitted,

/s/ John L. Abramic
John L. Abramic

Counsel for Appellee
Aquestive Therapeutics, Inc.

CERTIFICATE OF COMPLIANCE

I certify that this letter complies with the type-volume limitation of Fed. R. App. P. 28(j) as the body of the letter contains 345 words.

/s/ John L. Abramic
John L. Abramic

Counsel for Appellee
Aquestive Therapeutics, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2019, I caused the foregoing document to be electronically filed with the Clerk of the Court using CM/ECF, thereby serving it on all counsel of record via the CM/ECF system.

/s/ John L. Abramic
John L. Abramic

Counsel for Appellee
Aquestive Therapeutics, Inc.