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December 18, 2019

VIA CM/ECF

Col. Peter R. Marksteiner, USAF, Ret.
Circuit Executive and Clerk of the Court
U.S. Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington, DC 20439

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

Dear Colonel Marksteiner:

BioDelivery has filed a letter asking the Court to reopen its appeal based the Appointments Clause claim addressed in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). This Court entered on the docket a note stating: "Pursuant to Federal Rule of Appellate Procedure 44(a), the court certifies that a party questions the constitutionality of an Act of Congress." Unlike its practice in cases in which parties raised constitutional challenges earlier in the appellate proceeding, the Court did not issue an order giving the United States a period to intervene in this case.

BioDelivery's appeal here is from a denial of institution; institution decisions are not called into question under *Arthrex*. 941 F.3d at 1340 ("[W]e see no constitutional infirmity in the institution decision as the statute clearly bestows such authority on the Director pursuant to 35 U.S.C. § 314.").

Furthermore, because BioDelivery did not present this argument in its earlier appeal, much less its opening brief here, it is forfeited. *See id.* ("Appointments Clause challenges are 'nonjurisdictional structural constitutional objections' that can be waived when not presented." (citations omitted)); *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1173 (Fed. Cir. 2019) (precedential order) (rejecting attempt to raise Appointments Clause challenge based on *Arthrex* via post-opening brief 28(j) letter); *see also, SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006)

("Our law is well established that arguments not raised in the opening brief are waived.").

Given the irrelevance of BioDelivery's argument, its forfeiture, this Court's *Customedia* precedent, and the lack of an intervention order in this case, the United States does not understand the Court to be entertaining any constitutional challenge to the statutes governing the Patent Trial and Appeal Board. It is unnecessary, therefore, for the United States to intervene in this case under Federal Rule of Appellate Procedure 44 and 28 U.S.C. § 2403(a).

If the Court is nevertheless considering addressing BioDelivery's belated and irrelevant Appointments Clause challenge, the United States stands ready to respond to any order regarding intervention in this case this Court may issue.

Respectfully submitted,

/s/ Molly R. Silfen
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cc: Counsel of Record via CM/ECF

CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2019, I electronically filed the foregoing with the Court's CM/ECF filing system, which constitutes service, pursuant to Fed. R. App. P. 25(c)(2) and Fed. Cir. R. 25(e).

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