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December 27, 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: *Duke University v. Biomarin Pharmaceutical Inc.*, No. 18-1696

Dear Colonel Marksteiner:

The appellant has filed a letter asking the Court to remand this case based on the same Appointments Clause claim addressed in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. Oct. 31, 2019). In response, 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 at an earlier point in appellate proceeding, the Court did not issue an order giving the United States a period to intervene in this case.

Because appellant did not present this argument in its opening brief, it is forfeited. *See Arthrex*, 941 F.3d at 1340 (“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. Nov. 1, 2019) (precedential order) (rejecting patent owner’s attempt to raise Appointments Clause challenge based on *Arthrex* via post-opening brief 28(j) letter); *see also, e.g., 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 appellant’s forfeiture, this Court’s precedential order in *Customedia*, 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 considering addressing appellant's belated Appointments Clause challenge, notwithstanding the precedential ruling in *Customedia* that such challenges are forfeited by an appellant's failure to raise them in its opening brief, the United States stands ready to respond to any order regarding intervention in this case this Court may issue.

Respectfully submitted,

/s/Brian Racilla  
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cc: Counsel of Record via CM/ECF

### **CERTIFICATE OF SERVICE**

I hereby certify that on December 27, 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).

/s/Brian Racilla

Associate Solicitor

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