



VIA CM/ECF

November 5, 2019

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

Kia Freeman
Partner
T. 617-449-6549
F. 617-206-9412
kfreeman@mccarter.com

Re: Fed. R. App. P. 28(j) citation of supplemental authority in
BioDelivery Sciences Int'l, Inc. v. Aquestive Therapeutics, Inc. et al.,
Appeal Nos. 2019-1643, -1644, -1645

Dear Colonel Marksteiner:

McCarter & English, LLP
265 Franklin Street
Boston, MA 02110-3113
T. 617.449.6500
F. 617.607.9200
www.mccarter.com

Appellant BioDelivery Sciences International, Inc. (“BioDelivery”) writes to address the implications of *Arthrex, Inc. v. Smith & Nephew, Inc. et al.*, No. 2018-2140 (Fed. Cir. Oct. 31, 2019) on its pending Petition for Rehearing *En Banc*.

Arthrex found that a challenge under the Appointments Clause of the U.S. Constitution presented for the first time on appeal “was properly and timely raised” Slip op. 28. The Appointment Clause requires Principal Officers of the United States to be appointed by the President with consent of the Senate. *Arthrex* found that APJs are Principal Officers because they “exercise significant authority” (slip op. 8), and their work is not sufficiently directed and supervised by a properly appointed Principal Officer (slip op. 9). Since APJ appointments violated the Appointments Clause, *Arthrex* held that the unconstitutionally-derived decision in that appeal must be vacated.

Importantly, *Arthrex* found a constitutional violation, in part, because there had been “insufficient review within the agency over APJ panel decisions.” Slip op. 13. It recognized: “Panels of APJs issue final decisions on behalf of the USPTO, ...without any principal officers

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having the right to review those decisions.” Slip op. 12. “To be clear, the Director does not have the sole authority to review or vacate any decision by a panel of APJs.” Slip op. 11.

Arthrex did “not agree that the Director’s power to institute (ex ante) is any form of review (ex post).” Slip op. 12. Whereas the *BioDelivery* Order relies on an alleged inherent authority to reconsider, *Arthrex* recognized that a reconsideration decision is not a decision by or under authority of the Director, but rather a decision by APJs. Slip op. 10.

BioDelivery’s Petition emphasizes the importance of the Court’s authority to review decisions by APJs. *See* Petition at 6-7, 11, 14. *Arthrex*’s recognition that decisions by APJs were subject to insufficient review within the Office reinforces the importance of the Court’s review. *Arthrex* confirms that the Order granting the motion to dismiss BioDelivery’s appeal should be vacated. BioDelivery should have the opportunity to argue the merits of its appeal of unconstitutionally derived decisions by APJs.

Dated: November 5, 2019

Respectfully submitted,

/s/ Kia L. Freeman

Kia L. Freeman

Wyley Sayre Proctor

MCCARTER & ENGLISH, LLP

265 Franklin Street

Boston, MA 02110

Attorneys for Appellant

cc: Counsel of Record

CERTIFICATE OF COMPLIANCE

I certify that the foregoing letter of the Appellant complies with the requirements of Fed. R. App. P. 28(j) and that the part of the letter that begins with the first word after the salutation and ends with the last word before the complimentary close does not exceed 350 words, as determined by the word-count function of Microsoft Word.

Dated: November 5, 2019

Respectfully submitted,

/s/ Kia L. Freeman

CERTIFICATE OF SERVICE

I hereby certify that on November 5, 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(s).

Respectfully submitted,

/s/ Kia L. Freeman