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LONDON LOS ANGELES NEW YORK SAN FRANCISCO
SEOUL SHANGHAI SILICON VALLEY WASHINGTON

Christopher N. Sipes

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5525
csipes@cov.com

August 9, 2018

By CM/ECF

Peter Marksteiner
Circuit Executive and Clerk of Court
U.S. Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: *Momenta Pharm., Inc. v. Bristol-Myers Squibb Co.*, No. 17-1694 — Appellee Bristol-Myers Squibb's Rule 28(j) Letter re: *JTEKT Corporation v. GKN Automotive, Ltd.*, No. 17-1828 (Fed. Cir. Aug. 3, 2018) (available at --- F.3d ---, 2018 WL 3673005)

Dear Mr. Marksteiner:

This Court's recent decision in *JTEKT* further confirms that Momenta lacks Article III standing.

At the outset, *JTEKT* confirmed that the statutory provision permitting "an unsuccessful petitioner [to]…appeal an adverse final written decision…[,] cannot be read to dispense with the Article III injury-in-fact requirement for appeal to this court." Op. 3 (citing 35 U.S.C. § 141(c)); BMS Br. 35-36. Nor does the IPR statute's estoppel provision independently supply an injury-in-fact. Op. 7; BMS Br. 36. Instead, "the appellant/petitioner must show that it is engaged or will likely engage in an[] activity that would give rise to a possible infringement suit…." Op. 5 (quotation omitted); BMS Br. 26-27.

JTEKT then held that a petitioner lacked standing to appeal an adverse Board decision confirming the patentability of certain patent claims covering a drivetrain. Op. 2. JTEKT had no potentially infringing product on the market. Op. 5. "[W]here the party relies on potential infringement liability as a basis for injury in fact, but is not currently engaging in infringing activity, it must establish that it has concrete

plans for future activity that creates a substantial risk of future infringement or likely cause the patentee to assert a claim of infringement." Op. 5-6; BMS Br. 26-27, 32. But JTEKT's supporting declarations demonstrated only that "JTEKT and [the patentee] are competitors generally," JTEKT did not yet have a "finalized" product, and "JTEKT's product is in development and will continue to evolve." Op. 6 (quotation omitted).

The same is true of Momenta. Momenta is not currently engaging in infringing activity. BMS Br. 36 & n.12. Momenta has not even filed an application to enter the market with a biosimilar of BMS's Orencia®, BMS Br. 17-18, 26, 31-34, has recently reported the failure of its Phase I trial comparing an experimental product to Orencia®, BMS Mot. to Supplement 2 & Exh. 1, and its product may continue to evolve, BMS Br. 31-32. Thus, like JTEKT, Momenta "has not established at this stage of the development that its product creates a concrete and substantial risk of infringement or will likely lead to claims of infringement." Op. 7.

Respectfully submitted,

/s/ Christopher N. Sipes
Christopher N. Sipes
George F. Pappas
Megan P. Keane
Bradley K. Ervin
COVINGTON & BURLING LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001
Tel: (202) 662-6000
Fax: (202) 778-6000
Email: csipes@cov.com

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CERTIFICATE OF COMPLIANCE

The letter complies with the type-volume limitation set forth in Fed. R. App. P. 28(j) because the body of the letter contains 349 words.

Dated: August 9, 2018

/s/ Christopher N. Sipes
Christopher N. Sipes

CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2018, a true and correct copy of the foregoing was electronically filed with the Clerk of Court using the CM/ECF System, and that service upon the following counsel was accomplished using the CM/ECF System:

Deanne Maynard
Brian Robert Matsui
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Suite 6000
Washington, D.C. 20008
Tel: (202) 887-8740
Fax: (202) 785-7520
Email: dmaynard@mofo.com
Email: bmatsui@mofo.com

/s/ Christopher N. Sipes
Christopher N. Sipes

Dated: August 9, 2018