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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

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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<sup>®</sup>, BMS Br. 17-18, 26, 31-34, has recently reported the failure of its Phase I trial comparing an experimental product to Orencia<sup>®</sup>, 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

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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

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**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:

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/s/ Christopher N. Sipes  
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Dated: August 9, 2018