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October 3, 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) Response to Appellant Momenta Pharmaceuticals Inc.'s Rule 28(j) Letter regarding Momenta October 1, 2018 Press Release

Dear Mr. Marksteiner:

Momenta's October 1, 2018 Press Release confirms Momenta's lack of Article III standing from the commencement of this appeal. In the alternative, the Press Release indicates that Momenta may soon voluntarily moot the appeal.

Momenta's asserted injuries from the PTAB's Final Written Decision confirming the patentability of BMS's '239 patent rest on an attenuated chain of drug development and FDA approval contingencies for its proposed biosimilar of BMS's Orencia®. BMS Br. 31-33. Such hypothetical future harm falls short of the "certainly impending" injury-in-fact required by Article III. *Id*. at 33-34 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 402 (2013)). *See also* BMS Rule 28(j) Letter (submitting *JTEKT Corp. v. GKN Automotive, Ltd.*, 898 F.3d 1217 (Fed. Cir. 2018)). Momenta's October 1, 2018 Press Release underscores the uncertainty of Momenta's claimed injury.

Momenta announced that it "has initiated discussions with its collaboration partner, Mylan, to exit its participation in the development of . . . M834, a proposed

biosimilar to ORENCIA® . . . ." Press Release 1.[1] In short, Momenta is preparing to abandon the development of its purported biosimilar altogether, and is certainly not currently engaging in infringing activity, BMS Br. 36 & n.12, has not filed an application to enter the market with a biosimilar of BMS's Orencia®, BMS Br. 17-18, 26, 31-34, and has not even succeeded with a Phase I trial comparing an experimental product to Orencia®, BMS Mot. to Supplement 2 & Exh. 1. In these circumstances, Momenta is far from having established a concrete threat of infringement liability. BMS Br. 26-27.

Even had Momenta previously established an Article III injury-in-fact, the October 1, 2018 Press Release presages the imminent mooting of Momenta's appeal by eliminating Momenta's only theoretically infringing product. Momenta's voluntary discontinuance of its experimental product would both moot this appeal and preclude vacatur of the PTAB's decision. BMS Reply In Supp. of Mot. to Supplement 3 (citing cases).

Respectfully submitted,

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[1] Although Mylan is a real party in interest, it is not a party to this appeal or the underlying PTAB proceeding.

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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 339 words.

Dated: October 3, 2018

/s/ Christopher N. Sipes
Christopher N. Sipes

CERTIFICATE OF SERVICE

I hereby certify that on October 3, 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
Christopher N. Sipes

Dated: October 3, 2018