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June 14, 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 Pharmaceutical Inc.'s Rule 28(j) Letter regarding *Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, Inc.*, No. 17-1487 (Fed. Cir. May 2, 2018); *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018); and *AIDS Healthcare Found. v. Gilead Scis., Inc.*, No. 16-2475 (Fed. Cir. May 11, 2018)

Dear Mr. Marksteiner:

Momenta's proffered authorities do not support its Article III standing.

*Altaire* involved a dispute between parties to an agreement through which Paragon secured FDA approval of Altaire's existing products. Op. 3. After obtaining a related patent, Paragon sued to terminate the agreement. Op. 4-5. Altaire sought post-grant review of Paragon's patent for allegedly claiming Altaire's products. Op. 5-6. The Court held that Altaire had standing to appeal the PTAB's denial "under these circumstances" that made Altaire's injury "inevitable." Op. 12. These unique circumstances are inapposite to Momenta.

Altaire was already manufacturing its products under an FDA approval, Op. 3, 12, and intended to "resume marketing" those products directly if the parties' agreement terminated, Op. 12. Momenta is not close to filing for FDA approval, and it is highly uncertain whether it ever will. Indeed, Momenta's experimental

formulation failed a Phase 1 trial. BMS Mot. to Supp. 2. Thus, unlike the "inevitable" injury in *Altaire*, Op. 12, it is highly uncertain that Momenta will ever obtain FDA approval, let alone for a product implicating BMS's patent.

Momenta also mischaracterizes *Altaire*'s reasoning. First, *Altaire* does not indicate that Altaire was the "object" of the PTAB decision. Second, *Altaire* relied upon declaratory judgment standing decisions, Op. 11, under which Momenta lacks standing. BMS Br. 27-28. Third, *Altaire* did not involve the BPCIA's complex FDA approval and patent-dispute-resolution regime that delimits a cognizable injury-in-fact for biosimilars. *Id*. 27-30. Finally, *Altaire* refused to decide whether potential estoppel "is sufficient independently to establish standing." Op. 13.

Momenta's additional citations are likewise unavailing. *AIDS* confirms the similarity between Article III standing and declaratory judgment standards. *AIDS*, Op. 5; BMS Mot. to Dismiss 15 n.5. *SAS* and *Oil States* considered IPR operation and constitutionality, not whether the petitioner or the patent-at-issue is the "object" of an IPR for Article III purposes. *SAS*, 138 S. Ct. at 1352; *Oil States*, 138 S. Ct. at 1372. Still, *Oil States* indicates that an IPR is aimed at "an issued patent claim," *id*. at 1370, consistent with this Court's statements that the petitioner is not the IPR's object. BMS Br. 25.

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: June 14, 2018

*/s/ Christopher N. Sipes*
Christopher N. Sipes

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## CERTIFICATE OF SERVICE

I hereby certify that on June 14, 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: June 14, 2018