MORRISON | FOERSTER

425 MARKET STREET
SAN FRANCISCO
CALIFORNIA 94105-2482

TELEPHONE: 415.268.7000
FACSIMILE: 415.268.7522

WWW.MOFO.COM

MORRISON & FOERSTER LLP

BEIJING, BERLIN, BRUSSELS,
DENVER, HONG KONG, LONDON,
LOS ANGELES, NEW YORK,
NORTHERN VIRGINIA, PALO ALTO,
SAN DIEGO, SAN FRANCISCO, SHANGHAI,
SINGAPORE, TOKYO, WASHINGTON, D.C.

June 4, 2018

Writer's Direct Contact
+1 (202) 887.8740
DMaynard@mofo.com

By CM/ECF

Peter Marksteiner
Circuit Executive and Clerk of Court
United States 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
(Oral argument held Dec. 5, 2017, before Judges Newman, Dyk, Chen)

Rule 28(j) Letter re: *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, No. 17-1487 (Fed. Cir. May 2, 2018) (reported at 889 F.3d 1274); *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:

Recent decisions confirm Momenta's standing.

Altaire held a post-grant-review petitioner had standing to appeal a Board decision because its concrete plans were threatened by the challenged patent. Like Momenta, Altaire was a pharmaceutical company that previously "demonstrated its production and marketing capabilities." *Altaire*, Op. 12; Momenta Br. 15. Like Momenta, Altaire submitted testimony showing it planned to market a drug allegedly covered by the patent. Op. 10-11; Momenta Br. 15-16, 53-57. Altaire, like Momenta, had plans to seek FDA approval but had not yet (and Altaire might not for years). Op. 11-13; Momenta Br. 15-16. As here, a successful post-grant challenge would remove a definite roadblock to marketing. Op. 11-13; Momenta Br. 63-64. Like Momenta, Altaire was certain to be sued for infringement upon seeking FDA approval. Op. 12; Momenta Br. 54-55.

These facts demonstrated imminent harm, concrete and particularized. Op. 12-14. That harm was "compounded by the likelihood that [the petitioner] would be estopped from" raising the same challenge again. *Id.*; *see* Momenta Br. 59-60.

Altaire also is notable for what it does not do. It does not treat the petitioner as a third-party to the Board's decision. *See SAS*, 138 S. Ct. at 1355 (IPR petitioner is "master of its complaint" that "gets to define the contours of the proceeding"). *Contra* BMS Br. 25-27. *Altaire* does not require a pharmaceutical company to file an FDA application to show imminent harm. *Contra* BMS Br. 27-31. *Altaire* does not conflate injury-in-fact with the immediacy-and-reality standard for declaratory judgment suits. *Cf. AIDS*, Op. 8. *Contra* BMS Br. 23-38. Rather, it treats petitioner's appeal as one from harmful agency action—refusal to cancel "the grant of a public franchise" that restricts petitioner's freedom to operate. *See Oil States*, 138 S. Ct. at 1373 (IPR is "reconsideration" of agency action that "take[s] from the public rights of immense value").

The Board's decision here threatens greater harm than in *Altaire*. It threatens the millions Momenta already invested developing a biosimilar. Momenta Reply 19-20. Momenta's harm is not just imminent, it is actual: without reversal, Momenta must change plans and incur even greater costs. *Id.*

Respectfully submitted,

/s/Deanne E. Maynard
Deanne E. Maynard

cc: All Counsel (by CM/ECF)

dc-930553

CERTIFICATE OF COMPLIANCE

This letter complies with the type-volume limitation of Federal Rule of Appellate Procedure 28(j) because the body of the letter contains 350 words.

Dated: June 4, 2018

/s/ Deanne E. Maynard

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system on June 4, 2018.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: June 4, 2018

/s/ Deanne E. Maynard