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June 4, 2018

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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 Biotech, 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.

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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