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August 13, 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)

Response to Bristol Meyer-Squibb's August 9, 2018 Rule 28(j) Letter re: *JTEKT Corp. v. GKN Automotive, Ltd.*, No. 17-1828 (Fed. Cir. Aug. 3, 2018)

Dear Mr. Marksteiner:

BMS endorses *JTEKT*'s outcome while ignoring the law and facts. But those matter.

First, the law: *JTEKT* reaffirms that evidence of Article III standing comes in many forms, including plans to “engage ‘in an activity that would give rise to a possible infringement suit,’” substantial interests “affected by a determination of patent validity,” or evidence of being “an actual or prospective competitor.” Op. 4-5 (citations omitted). Article III does not require a party to “bet the farm” or risk damages. *Id.* Thus, the fact that a party “has no product on the market at the present time does not preclude Article III standing.” *Id.* Instead, a party with “concrete plans for future activity that creates a substantial risk of future infringement” has standing. Op. 5-6. And nothing in *JTEKT* changes that the estoppel provision can further support injury-in-fact. *Altaire v. Paragon*, 889 F.3d 1274, 1283-84 (Fed. Cir. 2018).

Second, the facts: the *JTEKT* appellant's “problem [wa]s that [its] declarations d[id] not establish that its planned product would create a substantial risk of infringing” the claims. Op. 6. The appellant “admit[ted]” it could not “‘definitely say whether or not it will infringe the [challenged] patent,’” and could only attest to “‘a risk to future development.’” Op. 6-7. On those facts, this Court held the appellant lacked standing. *Id.*

But *Momenta* has standing under *JTEKT*'s standard. Unlike there, *Momenta* showed *current* development activity, costing millions of dollars, on a formulation that *Momenta* conceded

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infringes the challenged patent claims; these facts remain unchanged. Momenta Reply 19-20; Arg. Rec. 1:25-1:35; Appx3521. As *JTEKT* recognized, Article III does not even require such a concession. Op. 7. And unlike in *JTEKT*, Momenta faces the near certainty of an infringement suit when it markets its competing drug. Momenta Br. 54-55. Also unlike any facts in *JTEKT*, the Board's patentability determination affects Momenta's concrete plans now. Momenta Br. 63-64.

BMS offers no response on this law or these facts. Instead, BMS would require parties in Momenta's position to bet the farm before being allowed in federal court. That is not the law. The Court should confirm Momenta's standing.

Respectfully submitted,

/s/Deanne E. Maynard

Deanne E. Maynard

cc: All Counsel (by CM/ECF)

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: August 13, 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 August 13, 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: August 13, 2018

/s/ Deanne E. Maynard