Filed: December 17, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

BIOGEN MA, INC.
Patent Owner.

Patent No. 8,399,514

Inter Partes Review IPR2018-01403

REPLY IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,399,514

Biogen attempts to leverage out-of-context quotes from the Federal Circuit's decision in *FWP IP APS v. Biogen MA Inc.* to argue against institution. There, the Federal Circuit held that the specification of Forward Pharma IP ApS's (FP) Publication No. WO 2006/0037342 (WO '342) did not provide written description support for the claims recited in Biogen's U.S. Patent No. 8,339,514 ('514 patent). No. 17-2109, 2018 WL 5292070 (Fed. Cir. Oct. 24, 2018). The Federal Circuit *did not* consider WO '342 as an obviousness reference. Nor did it hold that unexpected results render the claims of the '514 patent nonobvious. That is unsurprising. The parties did not argue obviousness or unexpected results on appeal. The disputed issue was written description. Biogen's overreading of the Federal Circuit's decision should not impact the Board's institution decision here.

I. THE FEDERAL CIRCUIT'S WRITTEN DESCRIPTION ANALYSIS DID NOT CONSIDER OBVIOUSNESS OR WEIGH ANY SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS.

Biogen overreaches in attempting to bolster its unexpected results case. The Federal Circuit did not decide whether the '514 patent was obvious, or consider arguments concerning any supposed secondary evidence of non-obviousness. The issue on appeal was written description. As the Board noted in the interference decision that the Federal Circuit affirmed, there is a significant difference between evaluating written description, on the one hand, and "what might have been obvious," on the other. Decision at 28, *Biogen MA Inc. v. Forward Pharma A/S*,

Interference 106,023 (PTAB Mar. 31, 2017), Paper 813. "Using the prior art in the way urged by FP *may show* that the claimed subject matter, when considered with the prior art, *might have been obvious to one skilled in the art*," even if it "fails to show . . . that FP's inventors had possessed and described the specific treatment method they now claim." *Id*. (emphasis added); *see also id*. at 24 ("[T]he written description requirement is met by describing the invention . . . not by merely describing that which would make the invention obvious.").

The distinction is critical, and the Federal Circuit only analyzed written description, not obviousness. On appeal, Biogen repeatedly criticized FP for taking an "obviousness-type approach[] to written description." Brief of Appellee at 50, *FWP IP APS v. Biogen MA Inc.*, No. 17-2109 (Fed. Cir. Nov. 16, 2017), ECF No. 31 ("Biogen Br."); *see also id*. at 19, 23-24. Faced with changed circumstances, Biogen should not be permitted to take a written description approach to obviousness here.

II. THE PARTIES DID NOT ARGUE, AND THE FEDERAL CIRCUIT DID NOT DECIDE, THE MERITS OF UNEXPECTED RESULTS.

The appeal record also does not support Biogen's argument that the Federal Circuit "confirmed" that Biogen's purported unexpected results are "significant." Paper 7 at 2. The parties did not argue the merits of unexpected results on appeal. For example, because it had no occasion to consider obviousness, the Federal Circuit did not consider whether any purported unexpected results were "different

in kind and not merely in degree from the results of the prior art," as is required for unexpected results to be "probative of nonobviousness." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013) (citation omitted).

Tellingly, on unexpected results Biogen's appeal brief cites only the Board's previous *inter partes* review decision, Biogen press releases, and its own motion. Biogen Br. at 5-6. The Federal Circuit's use of the term "unexpectedly," in turn, is limited to characterizing Biogen's arguments. *FWP*, 2018 WL 5292070 at *6. Importantly, the Federal Circuit did not have the evidence presented in Mylan's Petition demonstrating that prior to the filing of the '514 patent, skilled artisans would have understood that administering 480 mg/day of DMF was likely to be similarly efficacious in treating MS as 720 mg/day (*see e.g.*, Paper 2 at 54-55, 58-59), and that Biogen's unexpected results evidence is contradicted by other publications (*see also e.g.*, *id* at 55-58).

Different records often lead to different results. Here, not only are the records different, the substantive law is too. Biogen should not be allowed to bootstrap dicta from the Federal Circuit's decision in a case involving different evidence and legal issues to argue for non-institution of *inter partes* review.

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The Federal Circuit's written description holding does not support denial of institution of this *inter partes* review.

Dated: December 17, 2018

Respectfully submitted,

PERKINS COIE LLP

By: /s/ Brandon M. White

Brandon M. White
Reg. No. 52,354

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