Filed: December 24, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

IPR2018-01403
Patent No. 8,399,514

PATENT OWNER SUR-REPLY

The Federal Circuit's recent *FWP* decision confirms that Mylan is wrong about WO '342 and provides further support for denying institution. In its Petition, Mylan states that WO '342 "discloses daily doses of 480 mg of DMF, and describes therapeutic efficacy in treating MS." Pet., 32; *see also id*., 48-50. Because both the Board and the Federal Circuit have found that WO '342 *does not disclose* using 480 mg/day of DMF and/or MMF to treat MS, Mylan's obviousness challenge in Ground 3 must fail.

I. The Federal Circuit Decision Confirms That Mylan's Arguments Based on WO '342 are Wrong

At the time that Mylan prepared and filed its Petition, the parties were awaiting the Federal Circuit's decision in the *FP Interference*. The Board's interference decision *was available*, but Mylan chose to advocate a position in direct conflict with it.

In particular, Mylan argued that the Board had purportedly not considered "the disclosure of 480 mg/day DMF for the treatment of MS in WO '342." Pet., 65. But the Board evaluated WO '342 in the *FP Interference* and found the exact opposite: "[WO '342] does not indicate 480 mg/day is a therapeutically effective dose with respect to any condition or disease or is otherwise of any particular significance with respect to treatment of MS . . . ." *Biogen MA Inc. v. Forward Pharma A/S*, Intf. 106,023, Doc. 813 at 22 (PTAB Mar. 31, 2017) (Judges Schafer,

Katz, Lane) (Ex. 2030). Mylan made no effort to address or reconcile its position with the Board's prior decision.

The Federal Circuit's decision does not help Mylan. In *affirming* the Board, it confirms that Mylan's arguments regarding WO '342 are wrong. The Court concluded that WO '342 does not disclose Biogen's claimed invention. *FWP IP ApS v. Biogen MA Inc.*, No. 17-2109, slip op. at 13 (Fed. Cir. Oct 24, 2018). In addition, the Court concluded that the "prior art [cited by FP] does not teach the key limitation of the count: the 480 mg daily dosage." *Id.* at 14.

Mylan's Reply fails to address these conclusions, just as Mylan's Petition disregarded the Board's interference decision. Instead, Mylan attempts to downplay the decision in *FWP* by categorizing it as addressing only written description, not obviousness. Reply, 1-2. But any differences between the legal standards are irrelevant because the challenge in Mylan's Petition depends on WO '342 disclosing what the Board—and now the Federal Circuit—have held that it does *not* disclose, i.e., the 480 mg daily dosage of DMF and/or MMF for treating MS. *See, e.g.*, Pet., 65; Ex. 1002, 77 n.6.

II. *FWP* Supports the Denial of Mylan's Petition

Mylan argues that Biogen "overread[s]" the *FWP* decision when it comes to obviousness. Reply, 1. This is incorrect. During the *FWP* appeal, as Mylan admits, Biogen cited to the Court the Board's decision in *Coalition for Affordable Drugs V*

LLC v. Biogen MA Inc., IPR2015-01993 (PTAB Mar. 21, 2017) ("*Coalition II*") (Judges Schafer, Katz, Lane). *Coalition II* and the *FP Interference* were decided by the same Board panel on a coordinated schedule, resulting in contemporaneously issued decisions. Ex. 2030; Ex. 2038. In *Coalition II*, the Board weighed the evidence and found "that the *magnitude of clinical efficacy* of the 480 mg/day treatment would have been unexpected by those working in the art." Ex. 2038, 26 (emphasis added); *id.*, 2. In its POPR, Biogen referred to the Board's finding and the Federal Circuit's acknowledgement of Biogen's discovery. POPR, 2, 15-16; *FWP* at 14-15. It is appropriate for the Board to consider all proceedings relating to the patent in exercising its discretion to deny institution. *See, e.g.*, *NetApp Inc. v. Realtime Data LLC*, IPR2017-01195, Paper 9 at 11-13 (PTAB Oct. 12, 2017). The Federal Circuit decision thus supports denial of institution.

III. Conclusion

For the reasons set forth herein and in Biogen's POPR, the Board should deny Mylan's Petition.

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner Sur-Reply** was served electronically via e-mail on December 24, 2018, in its entirety on the following:

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