UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

Case IPR2020-00040
U.S. Patent 7,326,708

PATENT OWNER'S SUPPLEMENTAL BRIEF REGARDING *APPLE v. FINTIV*

I. The MDL Has Not Been Stayed And A Stay Is Unlikely.

The first factor favors non-institution. For good reason, no party in the ongoing MDL (including Mylan) has apprised the DE court of the Petition, much less sought a stay:[1] the MDL defendants assert a greater number of invalidity grounds, on a greater number of claims, than does the Petition, and Mylan's MDL co-defendants would not be bound by the result here. Paper 10 at 26–27. Moreover, extensive infringement discovery is required because no MDL defendant has stipulated to infringement of the '708 patent, including the claims Mylan seeks to cancel here. EX2014 ¶ 15. Put simply, the result of this IPR will neither substantively nor procedurally affect the MDL. The MDL court thus is unlikely to stay the case for this IPR, which involves just one of twelve defendants and will not resolve the litigation. *Plastic Omnium Adv. Innovation & Res. v. Donghee Am., Inc.*, No. 16-187-LPS (D. Del. Oct. 27, 2017), ECF No. 196 (EX2024). This is particularly true because the unchallenged '871 patent (that claims, *inter alia*, the sitagliptin molecule) expires in July 2022, EX1007; and district court judgments on the '708 and other patents are needed before expiry of the '871 patent and potential generic launch. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1283–84 (Fed. Cir. 2008).

[1] While the WV court was notified of the IPR, EX2019, the DE court has jurisdiction over the MDL and the WV court cannot stay those proceedings, EX2023.

II. Trials Will Take Place A Short Time After The Statutory Deadline.

This factor favors non-institution. Trial in DE will take place 5 months after the statutory deadline, with Mylan's trial in WV conditionally scheduled 2 months later. Paper 10 at 11. But that is not dispositive: critically, the Board's final written decision will not result in greater judicial efficiency. *Id.* at 24–31. Because Mylan and the other MDL defendants raised overlapping invalidity challenges over the same art that cannot be adjudicated here (*e.g.*, OTDP) and a majority of asserted claims are not addressed in the Petition, trial in both DE and WV will be necessary. If Merck prevails in the IPR, the DE trial will still encompass all IPR grounds. *Id.*

III. The Parties Have Invested Substantial Resources In The MDL.

This factor favors non-institution. After Mylan moved to dismiss the case on venue grounds, *see* EX2020, Merck refiled in WV and sought MDL consolidation before the JPML, *see* EX2021; EX2022; the JPML subsequently ordered consolidation, *see* EX2023. The DE proceedings are active. *See* EX2015. Substantial completion of document production is due April 22. To date, Merck has produced about 2 million pages; Mylan has produced over 20,000 pages; and the remaining defendants have produced nearly 700,000 pages. EX2014 ¶ 16. The parties have propounded numerous discovery requests and have spent substantial time responding to them and conferring in an attempt to resolve disputes. *Id*. Merck filed its opening *Markman* brief on March 20; defendants will file their brief on May 1; and a hearing

is scheduled for August 18, about 9 months before a final IPR decision. EX2006 at 7–8. Mylan's delay in filing its Petition also favors non-institution. Mylan served a Paragraph IV notice and statement that raised invalidity arguments over 9 years ago, EX2018 at 2–3, 33, yet did not file its Petition until 9 months after Merck filed suit (and even then on less than all asserted claims). This has "impose[d] unfair costs," *Fintiv* at 11, and is prejudicial. Paper 10 at 30–31.

IV. The Petition's Grounds Are A Small, Duplicative Subset Of The MDL.

This factor favors non-institution. Mylan has not disputed that all challenged claims are at issue in the MDL, the art and arguments are duplicative of the MDL invalidity contentions, and only a small fraction of the MDL arguments are addressed in this IPR. Paper 10 at 24–25; EX2008 at 8–9; *see also* Paper 13 at 5–7.

V. Merck And Mylan Are Active Litigants In The District Courts.

The parties are litigating actively, EX2014 ¶ 8–18, which favors denial.

VI. Hatch-Waxman, § 325(d), And The Merits Cut Against Institution.

This factor favors non-institution. The Hatch-Waxman Act provides a balanced, expedited path for drug companies to resolve patent disputes. 527 F.3d at 1294. There is no evidence that Mylan's Petition will lead to greater efficiency; the opposite is true. Paper 10 at 23–31. The Petition is also weak: its § 103 grounds rely on non-prior art, § 325(d) is implicated, and the Petition ignores the claimed 1:1 stoichiometry limitation. *Id.* at 31–54.

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Respectfully submitted,

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