IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

MERCK SHARP & DOHME CORP.
Patent Owner.

U.S. Patent No. 7,326,708 to Cypes et al.
Issue Date: February 5, 2008
Title: Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor

Inter Partes Review No.: IPR2020-00040

PETITIONER MYLAN PHARMACEUTICALS INC.'S SUPPLEMENTAL BRIEFING ON DISCRETIONARY DENIAL 35 U.S.C. § 314(A)

Factor 1 – No motion for a stay has been filed in the district court. However, the parties would be generally disincentivized to stay the concurrent litigation. As a Hatch-Waxman matter, an automatic statutory 30-month stay of FDA approval is in place. By statute, if "either party to the action fail[s] to reasonably cooperate in **expediting** the [district court] action" it could shorten or lengthen the statutory stay. 21 U.S.C. § 355(j)(5)(B)(iii). Further, the district court proceeding involves multiple defendants—distinguishing *Fintiv* (Paper 11 at 6 n.9), and emulating *Sandoz* (also a Hatch-Waxman matter). Paper 13 at 5. The other defendants will likely not agree to a stay. Finally, the district court would likely be disinclined to issue a stay because Merck has asserted another patent. On balance, this factor favors institution.

Factor 2 - The FWD is due at least **five months before** the district court trial. POPR, 26. As *Fintiv* noted, "as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC." *Fintiv*, 9. The same "practical" considerations exist if the PTAB finds the claims invalid. Since the FWD is due many months before trial, the district court has time to consider it and how it streamlines the issues before it. This factor favors institution.

Factor 3 - *Fintiv* focuses on the facts, as they would exist at the time of the Institution Decision. *Id*., 9-10. Here, institution is expected by May 14. At that time, there will be no substantive rulings from the district court. Joint Claim Construction Briefing is due **two months after**, and a *Markman* hearing is scheduled **three**

months after, the instant Institution Decision. *Fintiv*, 10 n.18. No depositions are scheduled (or have been taken) and the district court will not have considered invalidity issues before institution. Petitioner filed the Petition expeditiously—**five weeks** after possessing Merck's Infringement Contentions (September 23, 2019) and well before the § 315(b) one-year statutory window. EX2006; *Fintiv*, 11 n.21 (citing *Intel Corp.*, **eight weeks** is diligent). At filing, Mylan was not in possession of and therefore could not have used Merck's responses to Mylan's invalidity arguments. *Fintiv*, 12; Petition, 67; EX1015, 15-16. With its early filing, Mylan did not "impose unfair costs to patent owner." *Fintiv*, 11. This factor favors institution.

Factor 4 - In the district court, two patents have been asserted against Petitioner – the '708 patent and U.S. Patent No. 8,414,921. The subject matter of the two patents do not overlap. Further, in the district court, all claims of the '708 patent have been asserted against Petitioner while the Petition only challenges Claims 1-4, 17, 19, and 21-23. With respect to the '708 patent, Defendants' Invalidity Contentions assert additional statutory grounds of unpatentability including: obviousness-type double patenting, lack of written description, enablement, failure to comply with 35 U.S.C. § 112, paragraph 4, and 35 U.S.C. § 102(f). EX2008; *Fintiv*, 13 n.24 (citing *Chegg, Inc.*, noting different statutory grounds favor institution). With regard to the '921 patent, Defendants' Invalidity Contentions comprise invalidity under obviousness and pre-AIA § 112, second

paragraph. EX2008. The lack of overlap favors institution.

Factor 5 - The Mylan entities are the same (which is the typical case for most IPRs). The district court defendant and IPR petitioner tend to be the same because a non-litigating IPR filer may have appellate standing concerns. *General Electric Co. v. United Technologies Corp*., 928 F.3d 1349 (Fed. Cir. 2019). The parallel proceeding, however, involves a different defendant entity—more than 10 defendants. The lack of overlap in the defendant entity(ies) favors institution.

Factor 6 – Here, the grounds are "particularly strong on the preliminary record." *Fintiv*, 14, 15 n.29 (citing *Illumina,* explaining merits outweigh efficiency). The Petition includes, *inter alia*, two anticipation and one single-reference obviousness grounds. Merck's POPR provided neither a substantive rebuttal nor any countervailing expert testimony. With an unopposed expert, Mylan's arguments on the "preliminary record" are particularly strong. *Apotex Inc. v. UCB Biopharma SPRL*, IPR2019-00400 (Paper 17) at 18-19 (PTAB July 15, 2019) (noting unopposed expert testimony at the preliminary stage). The factor favor institution.

Other Considerations (*Fintiv, 16***) –** Merck is trying to antedate certain art for a subset of the grounds. POPR, 34. The USPTO's Examiners regularly deal with antedating issues, and by extension, the PTAB since it handles Examiner appeals. Paper 13 at 7 (citing PTAB cases). Given this familiarity, the PTAB is particularly well-suited to resolve these issues.

RESPECTFULLY SUBMITTED,

Katten Muchin Rosenman LLP

Date: April 14, 2020

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