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 SURREPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Nothing in Petitioner Mylan's Reply (Paper 13) changes that the balance of factors under 35 U.S.C. §§ 325(d) and 314(a) strongly favor the Board's exercise of discretion to deny institution. As to § 325(d), it is inconceivable that the Examiner did not consider the published application and patent on the sitagliptin compound given the spare record and their prominence in that record. Mylan does not dispute that the language of the statute plainly does not require a rejection for the Board to exercise its discretion on these facts. As to § 314(a), Mylan does not dispute that institution would lead to wasteful, expensive, and duplicative litigation in light of the parallel MDL proceedings in the district courts. Instead, Mylan's Reply improperly isolates various factors—contrary to *NHK Spring*—and relies on factually distinguishable case law. Finally, as to Merck's evidence antedating WO '498, Mylan's baseless evidentiary objections only further support the Board's exercise of discretion in this case to avoid needlessly duplicating complex discovery in a forum bound by strict statutory deadlines.

I. The Discretionary Factors as a Whole Favor Denial of Institution.

As explained in *NHK Spring*, "there is no 'intent to limit discretion under § 314(a) such that it is . . . encompassed by § 325(d)'"; the Board may "consider and weigh *additional factors* . . . under § 314(a)." IPR2018-00752, Paper 8 at 20 (P.T.A.B. Sept. 12, 2018) (emphasis added). *NHK Spring*'s analysis of these factors both individually *and* as a whole distinguishes this case from *Sandoz v.*

Pharmacyclics, where the Board observed that unlike in *NHK Spring*, "Patent Owner does not contend that the arguments advanced in the Petition are substantially similar to those made during prosecution." IPR2019-00865, Paper 8 at 11 (P.T.A.B. Sept. 26, 2019).

Here, analysis of the factors under both §§ 325(d) and § 314(a) together support denial. Merck squarely presented Mylan's primary art to the Examiner and explained its significance. Mylan's Petition, meanwhile, suffers from two fatal flaws: one (improper reliance on WO '498 as prior art for obviousness) dooms nearly half of its Petition on the merits, and the other (its failure to address the 1:1 stoichiometry) dooms it entirely. These factors, when considered against the backdrop of instituting in the face of an ongoing MDL, support the Board's exercise of discretion under both §§ 325(d) and 314(a), and together present a textbook case for a discretionary denial.

A. Mylan's Case Citations Do Not Shift the Weight of *Becton* Factors (a)–(e), Which Uniformly Favor Denying Institution.

Mylan's attempt to distinguish discretionary factors in isolation through non-controlling case law is unpersuasive. This case does *not* involve "mere citation of references in an IDS that were not applied by the Examiner." Paper 13 at 1. It is undisputed that WO '498 and the '871 patent share identical specifications and that Merck presented the crux of Mylan's merits argument to the Examiner in the specification of the challenged patent. "The Examiner presumably was aware of"

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