UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE
Patent Owners

Case IPR2017-00047
Patent 6,331,415

PETITIONER'S REPLY IN SUPPORT OF MOTION FOR JOINDER

Patent Owners' Response to Petitioner Merck's Motion for Joinder offers no reason why the present Petition (IPR2017-00047) should not be joined to IPR2016-00710 ("the Mylan IPR"). As such, Patent Owners tacitly concede that joinder is proper and should be granted.

Instead of objecting to Merck's request to join the Mylan IPR, Patent Owners use their Response to argue against institution of Merck's earlier-filed IPR2016-01373. According to Patent Owners, Merck's IPR2016-01373 should be not be instituted because of the potential for future estoppel under 35 U.S.C. § 315(e)(1). Aside from the fact that they lack standing to raise speculative estoppel arguments relating to another pending IPR petition, Patent Owners' interpretation of § 315(e)(1) is flawed for a number of reasons.

First, the plain language of § 315(e)(1) makes clear that any estoppel is applied on a claim-by-claim basis. 35 U.S.C. § 315(e)(1) ("The petitioner in an inter partes review ***of a claim*** in a patent under this chapter that results in a final written decision . . . may not request or maintain a proceeding before the Office ***with respect to that claim*** . . . .") (emphasis added). Here, there is not complete overlap between the challenged claims in Merck's IPR2016-01373 and IPR2017-00047. Specifically, IPR2016-01373 challenges claims 15-17 of the '415 patent, while IPR2017-00047 does not. Patent Owners' Response thus urges the Board to deny institution of Merck's IPR2016-01373 petition in its entirety based on a

misapplication of § 315(e)(1). Indeed, it would be manifestly unjust to deny Merck's IPR2016-01373 under these circumstances. Merck has a commercial interest in invalidating claims 15-17. In contrast, it appears that Mylan does not share that same commercial interest and thus did not seek invalidation of claims 15-17 in its IPR. Merck's separate petition should not be denied because some, but not all, of the claims at issue might be invalidated in the present proceedings.

Second, Patent Owners' arguments are inconsistent with the language of § 315(e)(1) as well as Federal Circuit case law. Estoppel under § 315(e)(1) attaches only as to "any ground that the petitioner raised or reasonably could have raised during that inter partes review." 35 U.S.C. § 315(e)(1). In *Shaw Indus. Group, Inc. v. Automated Creel Sys., Inc.*, 817 F.3d 1293, 1299-1300 (Fed. Cir. 2016), the Federal Circuit held that estoppel under § 315(e)(1) does not apply to grounds presented in an IPR petition but not instituted by the Board. The Federal Circuit explained that "[t]he IPR does not begin until it is instituted" and that "the plain language of the statute prohibits the application of estoppel under these circumstances" because the petitioner could not have reasonably raised the uninstituted grounds in the petition ***during*** the IPR. *Id.* at 1300 (emphasis in original).

Here, Merck could not have raised or reasonably raised the grounds currently asserted in IPR2017-00047 in its earlier-filed IPR2016-01373. When

Merck filed IPR2016-01373 on July 7, 2016, the Board had already instituted two IPR petitions on the exact grounds raised in the Mylan IPR and in IPR2017-00047. *See* IPR2015-01624 ("the Sanofi IPR"), Paper 15; IPR2016-00460 ("the Genzyme IPR"), Paper 12. At that time, it was too late for Merck to join the Sanofi and Genzyme IPRs. *See* 37 CFR § 42.122(b). Had Merck presented the grounds it now asserts in IPR2017-00047 in its earlier IPR, that petition would almost certainly have been denied based on 35 U.S.C. § 315(d) because those grounds would have been duplicative of the then-pending Sanofi and Genzyme IPRs. Moreover, there was no need for Merck to pursue those grounds as they were already part of two instituted IPRs and the Board was scheduled to issue a final written decision on those grounds in early 2017. Thus, it would not have been reasonable for Merck to present in IPR2016-01373 the grounds it now presents in IPR2017-00047.

After Merck filed IPR2016-01373, Patent Owners entered into settlement agreements with Sanofi and Genzyme and the Sanofi and Genzyme IPRs were dismissed before the Board issued a final written decision. IPR2015-01624, Papers 39-42; IPR2016-00460, Paper 13. Following these dismissals, the Board then instituted the Mylan IPR. It was only after institution of the Mylan IPR that Merck had the proper procedural opportunity to reasonably raise the grounds in the Mylan, Sanofi, and Genzyme IPRs, which it did via IPR2017-00047 and its motion

for joinder. Just as Merck could ***not*** have reasonably raised these grounds raised in its IPR2016-01373, Merck could not have reasonably raised the grounds from its IPR2016-01373 in its subsequently-filed IPR2017-00047 due to limitations against adding or altering arguments or expanding the already-instituted grounds of unpatentability on joinder. *See, e.g., Samsung v. Arendi*, Case IPR2014-01144, 2014 Par. App. LEXIS 6121 (Oct. 2, 2014) at *6 (denying joinder where the joining petition's declaration introduced "argument and evidence that was not presented in" the initial petition). Had Merck raised its earlier grounds in IPR2017-00047, joinder would have been inappropriate and IPR2017-00047 would have simply been dismissed as duplicative of the Mylan IPR and/or Merck's earlier-filed IPR2016-01373.

Thus, contrary to Patent Owners' allegations, there was simply no time when Merck could have reasonably raised in one petition both sets of grounds now before the Board on the '415 patent. Accordingly, under both the plain language of the statute and the holding in *Shaw*, estoppel under § 315(e)(1) is not applicable to IPR2016-01373, as Patent Owners contend. Indeed, Patent Owner's arguments, would frustrate Congress's stated goal for IPRs, namely facilitating Board of "questionable patents" via "novel challenges." *See* H.R. Rep. No. 112-98 (2011), reprinted in 2011 U.S.C.C.A.N. 67 at 46-48 (explaining that IPRs are "not [intended] to restrict novel challenges of questionable patents.")

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