

IPR2024-00009
U.S. Patent 10,335,462

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
and
DR. REDDY'S LABORATORIES, LTD.,

Petitioners

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2024-00009
Patent 10,335,462

PATENT OWNER'S SUR-REPLY

Petitioner’s “Reply” is largely unresponsive to Patent Owner’s (“PO”) *Fintiv* analysis in its POPR, and fails to show *Fintiv* does not support denial—including because Petitioner’s stipulation is **not** a *Sotera* stipulation as addressed in the Director’s *Fintiv* guidance. *Fintiv* denial is proper and should result here.

Factor 1. Petitioner does not dispute that it is highly unlikely the Delaware Litigation will be stayed. Indeed, Petitioner does not even argue it will seek a stay, and does not dispute that the Court would disfavor staying the Delaware Litigation. This factor is not neutral: rather, it favors denial. POPR, 7-9.

Factor 2. Petitioner does not dispute that the Delaware trial is scheduled to precede Mylan’s current FWD deadline. Instead, Petitioner speculates trial might move “a little bit” before chastising PO for speculating about “delay” in receiving a FWD. But even setting aside the Board’s obligation to “take courts’ trial schedules at face value absent some strong evidence to the contrary” (*Samsung v. Ancora*, IPR2020-01184, Pap.11, 21), Petitioner ignores that—even per Petitioner—the “delay[ed]” trial date and original FWD would be close in time, and that after joinder the FWD would have **no statutory deadline**. *Fintiv*, IPR2020-00019, Pap.11, 9; §316(a)(11); §42.100(c). Petitioner also does not address Petitioner’s cited *Memory Integrity* joinder decision, resulting in a FWD more than 13 months after institution. Compare IPR2015-00163, Pap.18 (May 8, 2015), with IPR2015-00163, Pap.52 (June 21, 2016). This, again, favors denial. See also POPR, 9-13.

Factor 3. Petitioner does not dispute that the parties have already invested significantly in the Delaware Litigation, which weighs heavily in favor of denial. *See* POPR, 13-17. Petitioner instead asserts this favors institution because certain challenged claims are not asserted in the litigation. But Petitioner ignores PO’s stipulation about assertion of non-overlapping claims in litigation, and that, accordingly, ***there is no such issue here***. POPR, 22 n.9. Further, Petitioner’s citation of *Samsung Bioepis Co. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00739, Pap.9, 57 (Oct. 20, 2023) is inapposite. Unlike here, that IPR involved little overlap in claims (only two of twelve challenged claims were asserted in the litigation), and ***a non-overlapping independent claim***. Moreover, Petitioner’s assertion here that claims 2 and 6 are not at issue in the Delaware Litigation is simply incorrect under *Samsung* given that claims 3 and 7 (which depend from 2 and 6) are asserted.

Factor 4. Petitioner’s February 21, 2024 “do-over” stipulation is not a *Sotera* stipulation as addressed in the Director’s *Fintiv* guidance because it was filed by Petitioner ***as a joining party*** and thus does not ensure avoidance of overlap between the IPR and litigation here. *See USPTO Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* at 7-8 (USPTO, June 21, 2022). Indeed, if instituted and joined, Petitioner can be expected to argue “could have reasonably been raised” in its new stipulation is a nullity based on *Network-1 Technologies, Inc. v. Hewlett-Packard Co.*, 981 F.3d

1015, 1026-28 (2020)—meaning (1) Petitioner is not estopped the way an original petitioner would be estopped by a *Sotera* stipulation because Petitioner (unlike an original petitioner) can raise any argument in litigation that was not actually raised in the original IPR, and (2) Petitioner’s new stipulation has the same inadequate impact as Petitioner’s original *Sand Revolution* stipulation (Pet.65). And the presence of other litigation defendants who are not subject to *any* stipulation belies any promise that the grounds in the PTAB will differ from those in the litigation.

Factor 5. Petitioner argues Factor 5 “should only play a role where a Petitioner is unrelated to a defendant in a district court proceeding” in asserting this factor should be neutral. Pet’r’s Rep., 2-3. But that is not what *Fintiv* says. IPR2020-00019, Pap.11, 14. Indeed, the Board’s *Fintiv* institution decision found that, “[b]ecause the petitioner and the defendant in the parallel proceeding *are the same party*, this factor weighs in favor of discretionary denial.” *Fintiv*, IPR2020-0019, Pap.15, 15 (May 13, 2020). Here, too, Factor 5 weighs in favor of denial.

Factor 6. Finally, Petitioner cannot overcome the other *Fintiv* factors and show “compelling merits” simply by arguing Mylan’s petition met the basic threshold for institution. *See* POPR, 23-24. Moreover, Petitioner simply ignores PO’s stated intent to swear behind prior art and argue objective indicia, and fails to address Petitioner’s unexplained delay in filing an IPR. *See* POPR, 23-24.

Respectfully submitted: /Mega Raymond/
Megan Raymond

March 6, 2024

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of NOVO NORDISK'S SUR-REPLY have been served in their entirety on March 6, 2024, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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