UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner

v.

NOVO NORDISK A/S,
PATENT OWNER

CASE IPR2024-00631
U.S. PATENT NO. 10,335,462
ISSUED: JULY 2, 2019

TITLE:
USE OF LONG-ACTING GLP-1 PEPTIDES

APOTEX'S REPLY TO PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR JOINDER

PROTECTIVE ORDER MATERIAL

Apotex replies to Novo's opposition to Apotex's motion for joinder or alternatively, consolidation. *See* Paper Nos. 5, 9. As for joinder, Novo principally contends that Apotex failed to show good cause for its motion and improperly waited to file it. [redacted] And Novo has shown no strategic advantage or improper purpose relating to the timing of Apotex's filings, because, quite simply, there was none. As for consolidation, Novo oddly asserts that scheduling issues preclude merging this proceeding with Mylan's, even though Apotex will serve as an understudy and follow the Mylan proceeding's schedule. Overall, Novo has not disputed that joinder or consolidation would promote efficient resolution of the cases or identified any prejudice resulting from either approach. The Board should thus grant Apotex's motion.

NOVO DOES NOT DISPUTE THAT *KYOCERA* FAVORS JOINDER

To begin, Novo does ***not*** dispute that the following *Kyocera* factors favor joinder: Apotex's petition presents no new unpatentability grounds, joinder will not impact the lead case's schedule, and briefing and discovery may be simplified.

Mot. 6-9. Novo even acknowledges that Apotex agreed to essentially the same conditions that resolved Novo's opposition to DRL's and Sun's motions for joinder to the Mylan proceeding. Opp. 7-9 n.5. Moreover, Novo has identified ***no*** prejudice that would result from joinder. In sum, the fact that these factors undisputedly favor Apotex, coupled with the absence of prejudice, compel joinder.

THE BOARD SHOULD WAIVE THE JOINDER TIMING REQUIREMENT

Novo argues that Petitioner has not shown "special" circumstances to justify waiving the joinder deadline. Opp. 1-3. But Apotex has shown exactly such circumstances. [redacted]

[1] [redacted]

[redacted]

[2] In light of these efforts, Novo's assertion that preparing a copycat petition "required no substantive work" is unfounded. Opp. 5-6.

[3] The "waiting" cases Novo cites are off point. In *Roche*, petitioner relied upon an acquisition to explain its delay despite filing its joinder motion over 4 months after publicly announcing the acquisition. *Roche*, IPR2015-01091, Paper No. 18, at 10-11. In *Shaw*, petitioner strategically waited for a Board rehearing decision prior to filing its motion. *Shaw*, IPR2013-00584, Paper No. 20, at 4-5.

[redacted][4]

Novo attempts to distinguish *GlobalFoundries* and *Sony*, cases in which the Board waived the filing deadline, on the basis that the petitioners in those cases attempted to join the earlier IPR proceeding within the filing deadline. Opp. 6-7. [redacted]. And critically, Novo ignores the key similarities between those cases and this one, *viz.*, that the petitions raised no new unpatentability grounds, the trial schedule did not need to be adjusted, and the petitioners agreed to serve as silent understudies. *Id*. at 10.

As a throwaway, Novo asserts that Apotex's motion was unauthorized. Opp. 1 n.1, 9. But seeking authorization was unnecessary, because Apotex filed its motion with its petition. *See* Trial Practice Guidelines at 37 (providing that prior

[4] [redacted]

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