

PROTECTIVE ORDER MATERIAL

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 PRELIMINARY RESPONSE

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Novo makes two main arguments against institution of Apotex's petition:

(1) discretionary denial is appropriate because Apotex filed an untimely "me-too" petition and (2) Apotex purportedly failed to address objective indicia raised in Novo's Patent Owner Response in the Mylan IPR. *See generally* POPR. Both arguments fail for the same reason: Like Sun and DRL, Apotex filed an IPR petition substantially similar to Mylan's so that it could serve as a silent understudy and minimize any impact on the pending Mylan IPR proceedings. In fact, had Apotex raised new arguments, e.g., addressing objective indicia, Novo would have assuredly argued that any differences in Apotex's petition relative to Mylan's would have justified denying institution of Apotex's petition. The Board has now instituted review in favor of Mylan, Sun, and DRL based on the substance of the Mylan petition. Apotex respectfully requests that the Board do so again here.

INSTITUTION SHOULD NOT BE DENIED UNDER §314(a)

Novo argues that institution should be denied because Apotex has filed an untimely me-too petition. POPR 2, 5-11. This argument, which is largely a rehash of Novo's arguments against joinder, Paper No. 9 at 1-8, is without merit. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

And Novo ignores that Apotex has also filed a consolidation motion, which has no timing

requirement. Paper No. 5 at 11-12; Paper No. 10 at 5. As for the fact that Apotex filed a me-too petition, the similarity of arguments favors institution *not* denial, because it permits Apotex to serve as a silent understudy, promoting efficient resolution of Apotex's IPR. As for Novo's citation to *Samsung v. Unilloc*, that case is distinguishable in that the petitioner in that case failed to file joinder or consolidation motions, depriving the Board of the resulting efficiencies, e.g., consolidated filings and discovery. Paper No. 5 at 6-9, 11-12; Paper No. 10 at 1-2.

Turning to the *General Plastic* factors, Factor 1 favors institution, as Apotex has not previously filed a petition to the same claims of the '462 patent, and has no significant relationship with prior petitioners. Pet. 66; *Amazon.com, Inc. v. Jawbone Innovations, LLC*, IPR2023-00284, Paper No. 12 at 10 (PTAB May 15, 2023). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] For all of these reasons, Factor 1 favors institution.

Despite conceding that Factors 2-5 “may not be considered since Apotex itself is a first-time petitioner,” POPR 15 n.5, Novo nonetheless argues that those

factors should be considered and weigh against institution, *id.* at 15-22. But even if those factors apply, they *favor* institution, because Apotex did not roadmap but instead filed a me-too petition. Pet. 67 (citing *Amazon.com*, IPR2023-00284, Paper No. 12 at 10). And Novo’s allegations that Apotex may roadmap in the future are speculative and meritless. POPR 18-19, 22-23. For example, Novo relies on confidential commercial success and swear-behind evidence, *see e.g., id.* at 3-5, which Apotex cannot access, let alone use to roadmap. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As to Factor 6, Novo argues that institution would unduly burden the Board, particularly given the “volume and complexity of evidence and issues in the Mylan IPR.” POPR 10-11, 22-24. But Apotex seeks to serve as Mylan’s understudy, such that institution would *not* burden the Board in view of the many conditions Apotex has agreed to as part of assuming that role. Paper No. 5 at 9. As to Factor 7, Novo asserts that the FWD deadline may be extended if Apotex’s petition is instituted, pointing to two scheduling extensions entered in the Mylan IPR. POPR 25-26. But, undermining its argument, Novo admits that the FWD “could come as soon as approximately October 4,” the *current* FWD deadline. *Id.* at 23 n.7.

APOTEX NEED NOT HAVE ADDRESSED OBJECTIVE INDICIA

Novo argues that institution should be denied because Apotex's petition failed to address the objective indicia that Novo raised in its Patent Owner Response in the Mylan IPR. POPR 26-29; *see also id.* at 3-4. This argument fails for multiple reasons. **First**, Apotex need not have addressed those indicia, as they "were not relied upon and decisive in prior proceedings." *Lab. Corp. of Am. Holdings v. Ravgen, Inc.*, IPR2021-01026, Paper No. 11 at 41 (PTAB Dec. 14, 2021). **Second**, Apotex seeks to become a silent understudy to Mylan, and Mylan had not yet addressed the indicia in its Reply when Apotex filed its petition here. **Third**, Novo oddly criticizes Apotex for not addressing objective indicia arguments, when Novo itself has not raised such arguments in its POPR in *this* proceeding, instead wholesale cross-referencing its Patent Owner Response and declarations from the Mylan IPR. POPR 3-4, 28. And Novo may not do so in its sur-reply, which "may not be accompanied" by declarations or documentary exhibits. 37 CFR §42.23(b). **Fourth**, if the Board believes that Apotex must address those indicia, Apotex relies on the positions of Mylan and its experts, consistent with a silent understudy role. *Mylan Pharms., Inc. v. Novo Nordisk, A/S*, IPR2023-00724, Paper No. 53 (PTAB May 22, 2024); Exs.1302-08.

For these reasons and those in Apotex's petition, Apotex respectfully requests that the Board institute *inter partes* review.

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Dated: July 1, 2024
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CERTIFICATE OF SERVICE

The undersigned certifies that, in accordance with 37 C.F.R. § 42.6(e) and 37 C.F.R. § 42.105, and with Patent Owner's consent, electronic service of APOTEX'S REPLY TO PATENT OWNER PRELIMINARY RESPONSE was made on Patent Owner to the following email addresses:

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