

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
Patent 10,335,462

**PATENT OWNER'S REPLY TO PETITIONER'S REPLY TO PA-
TENT OWNER'S PRELIMINARY RESPONSE**

PROTECTIVE ORDER MATERIAL -- FILED UNDER SEAL

LIST OF EXHIBITS

Exhibit	Description
EX2001	Docket Sheet from PTACTS, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724
EX2002	Joint Stipulation to Modify Due Dates 2, 3, 4, 5, 6, 7 and 8, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724 Paper 47
EX2003	June 7, 2024 Joint Stipulation to Modify Due Dates 3, 4, 5, 6, 7 and 8, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Paper 56
EX2004	Excerpted Patent Owner's Response, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Paper 30
EX2005	Excerpted Declaration of George L. Bakris, M.D., <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, EX2011
EX2006	Excerpted Declaration of Robin S. Goland, M.D., <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, EX2054
EX2007	Excerpted Declaration of Michael J. Blaha, M.D., <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, EX2055
EX2008	Excerpted Declaration of Christopher A. Vellturo, Ph.D., <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, EX2300
EX2009	Excerpted Declaration of Patrick J. Sinko, Ph.D., <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, EX2056
EX2010	June 10, 2024 Email from Counsel for Petitioner re: IPR2024-00631
EX2011	<i>Patent Exclusivity for N209637 (Semaglutide/Ozempic)</i> , Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, U.S. Food & Drug Administration, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=209637&Appl_type=N
EX2012	Declaration of Sayem Osman
EX2013	June 27, 2024 Email from Counsel for Petitioner re: IPR2024-00631 - request regarding reply to patent owner preliminary response

General Plastic. Petitioner’s “Reply” is largely unresponsive to PO’s *General Plastic* analysis, and fails to show *General Plastic* does not support denial. As an initial matter, Petitioner cannot meaningfully distinguish *Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2018-01756, Pap.7 (Mar. 11, 2019), which favors denial. Petitioner’s attempts to distinguish *Samsung* by pointing to Petitioner’s untimely, unauthorized joinder motion, and its related attempts to excuse itself from making a timely filing based on its **business decision** to delay, fail. Petitioner also ignores that institution is decided **before** joinder: the Board “**first determine[s]** whether application of the *General Plastic* factors warrants the exercise of discretion to deny the Petition under §314(a).” *Apple Inc. v. Uniloc 2017 LLC*, IPR2020-00854, Pap.9, 5 (Oct. 28, 2020) (precedential). And even if *Samsung* were ignored in favor of a factor-by-factor *General Plastic* analysis, Petitioner’s arguments fail.

Factor 1. [REDACTED] And Petitioner’s self-serving assertion that it “is **unaware of** any significant relationship” (Pap.17, 2) is unsupported and effectively meaningless: this factor favors denial. *See* POPR.12-13. Further, even assuming, *arguendo*, Petitioner has no relationship with Mylan, DRL, or Sun, Petitioner does not dispute that factor 1 would be entitled to minimal weight given the *complete overlap of grounds* raised in this IPR and Mylan’s. POPR.13-15. And *Amazon.com, Inc. v. Jawbone Innovations, LLC*, IPR2023-00284, Pap.12, 10 (May 15, 2023) (“*Amazon*”) (cited at Pap.17, 2),

is clearly distinguishable because the copycat petition and joinder motion there were *timely*. *See id.* at 9 (emphasizing copycat petition was “timely filed”).

Factors 2-5. Petitioner does not admit or provide evidence of how early it became aware of the references it now asserts, which weighs in favor of denial. *See* POPR.17-18. In any event, Petitioner does not dispute (1) that it was tracking the '462 Patent and the Mylan IPR at least five months before it filed the Petition, or (2) that it reasonably should have known of the references it asserts here. POPR.15-17. Petitioner instead argues the timing of its knowledge and explanation for its delay are *excused* because it's a copycat petitioner. Pap.17, 3 (citing Pet.67). But again Petitioner cites no case supporting its assertion in the context of a *late* joinder motion. Indeed, *Amazon* is inapposite given that, as noted in the Board's analysis of factors 2, 4, and 5, “Petitioner acted within the time frame set forth under our Rules.” *Amazon*, Pap.12, 10. And, of course, Petitioner has not asked the Board to deny institution here if joinder is denied (as it should be), setting up a petitioner-side re-do of the Mylan IPR with this Petitioner enjoying immense and improper roadmapping opportunities. To curtail potential abuse arising from Petitioner's untimely petition filed with the foresight of the POR, *General Plastic* and its progeny teach examining the “*potential* benefit” and the “*opportunity*” to roadmap—not just whether Petitioner actually ends up altering its arguments based on the available information, as Petitioner suggests. Pap.17, 3. *Gen-*

eral Plastic Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Pap.19, 16-17 (Sept. 6, 2017) (precedential); *3M Co. v. Bay Materials, LLC*, IPR2023-00243, Pap.8, 9 (July 7, 2023) (“3M”) (“opportunity” to roadmap favors denial under Factor 3). Further, Petitioner’s argument that it cannot roadmap because it cannot access commercial success or swear behind evidence ignores (1) that meaningful portions of the arguments and evidence on those issues are not sealed, (2) that it was able to roadmap using the vast arguments and evidence on other issues, and (3) that it would certainly have the going-forward opportunity to roadmap if instituted. Pap.17, 3; EX2004, 3; *Mylan IPR* (IPR2023-00724), Pap.10 (Oct. 4, 2023). While PO acknowledges the Board might choose not to consider these factors (POPR.15 n.5), Petitioner points to no precedent showing that the Board should ignore them.

Factors 6 and 7. Petitioner’s factor 6 and 7 analysis again *assumes* joinder and ignores that institution is decided *before* joinder. POPR.5-6; Pap.17, 3. Petitioner does not address the burden of a second, potentially-unjoined IPR, especially given the expected complexity and volume of the record, and where a timely joinder motion was not filed (and consolidation would be entirely impractical). POPR.3-5, 22-26. Further, Petitioner fails to address that without a timely joinder motion, it effectively presents “multiple, staggered petitions challenging the same patent and same claims,” which “[a]s a general rule” are “unfair to patent owners and... an inefficient use of the *inter partes* review process” and causes the Board

and PO to divert resources outside of the window established to address timely copycat petitions. *3M*, Pap.8, 10-11.

Objective Indicia. Petitioner does not dispute that it was aware of evidence of objective indicia and did not address it in the Petition. That Mylan hadn't yet filed its reply in the Mylan IPR by the time the Petition here was filed is irrelevant to Petitioner ignoring the detailed analysis and evidence in the POR filed over six weeks before the Petition. EX2004. Petitioner's attempt to improperly incorporate by reference the substance of Mylan's later arguments not only goes beyond the parties' agreement regarding the scope of supplemental briefing (EX2013), but also ignores that Petitioner knew of objective indicia, delayed filing its Petition, and filed its late Petition without addressing those known objective indicia.

Petitioner's case law, *Laboratory Corp. of America Holdings v. Ravgen, Inc.*, is inapposite—including because the petitioner there did not have access to the patent owner's response discussing objective indicia in detail. IPR2021-01026, Pap.11, 41 (Dec. 14, 2021). Moreover, the *Lab. Corp.* panel explicitly limited its holding to "th[at] record," acknowledging that not all prior decisions *denying* institution for failure to address known objective indicia required the evidence to have been "clearly relied upon and decisive in prior proceedings." *Id.*

Respectfully submitted: /Megan Raymond/

July 15, 2024

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER'S REPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE has been served in its entirety by causing the aforementioned document to be electronically mailed to the following attorneys of record for the Petitioners listed below:

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Dated: July 15, 2024

Respectfully submitted,

By: /Sayem Osman/
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