

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 PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107**

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

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I. Introduction

As detailed in this §42.107¹ Preliminary Response by Patent Owner Novo Nordisk A/S (“PO”/“Patent Owner”), Petitioner Apotex Inc.’s (“Petitioner”/“Apotex”) copycat Petition (“Petition”/“Pet.”) should be denied. First, the Board should exercise its discretion to deny the Petition under §314(a) and *General Plastic*. Petitioner Apotex was aware of and tracking IPR2023-00724 (the “Mylan IPR”), and asserts the ***very same grounds and arguments*** that were brought in the instituted Mylan IPR, but did not seek *timely* joinder. Pet.1, 5; EX1507, ¶2. As reflected in PO’s Opposition (Pap.9), Apotex’s late joinder request should be denied, and a duplicative proceeding would be wasteful, and the §314(a) *General Plastic* factors weigh in favor of denial. Second, Petitioner has not shown a reasonable likelihood of prevailing on its obviousness grounds (on which it relies for most of the challenged claims) because it has not addressed how it can overcome the objective evidence of non-obviousness presented in detail in the POR in the Mylan IPR, which Petitioner is clearly aware of but largely ignores.

¹ Unless stated, all statutory and regulatory citations are to 35 U.S.C. or 37 C.F.R., as context indicates, and all emphases/annotations are added.

II. Factual Background

A. Mylan's IPR and Apotex's Choice to File a Late Copycat Petition

On March 16, 2023, Mylan filed an IPR challenging the validity of U.S. Patent No. 10,335,462 (“’462 Patent”). That IPR was instituted for trial on October 4, 2023. Pap.10. The Mylan IPR is the subject of two previous copycat petitions, *Dr. Reddy's Laboratories, Inc. v. Novo Nordisk A/S*, IPR2024-00009 (“DRL IPR”) and *Sun Pharmaceutical Industries Ltd. v. Novo Nordisk A/S*, IPR2024-00107 (“Sun IPR”). Both of those petitions were filed along with timely joinder motions within a month of institution of the Mylan IPR. *DRL IPR*, Pap.19, 12 (Apr. 25, 2024) (“[DRL] timely filed [its] Motion no later than one month after institution of the Mylan IPR.”); *Sun IPR*, Pap.16, 12 (May 28, 2024) (same).

Apotex continued monitoring the Mylan IPR, and waited until March 1, 2024, some five months after the Mylan IPR's institution, to file the instant copycat Petition along with an unauthorized, four-month-late, joinder motion.² Pet.85; Pap.5; §42.122(b). [REDACTED]

[REDACTED] See EX1507, ¶2.

² Apotex filed its motion without the Board's permission despite having missed the deadline to file a joinder motion as of right. §42.20(b).

B. The Progress of the Mylan IPR Over the 8 Months Since Its Institution

As the first 8 months since institution have demonstrated, the Mylan IPR is far from a “standard” IPR in terms of its complexity, the number of witnesses presenting testimony, and the volume of its evidentiary record. The parties to that IPR have filed 641 exhibits, including 15 expert declarations (amounting to 1,356 pages), and have thus far taken ten depositions (with six more depositions noticed based on Mylan’s Reply declarations). EX2001. The schedule for the Mylan IPR (including the final hearing date) has been extended twice to accommodate the numerous depositions and voluminous declarations, and the word count limits for the POR, Reply, and Sur-Reply have also been increased—all for good cause to allow the parties to address the many issues raised there including swear behind and secondary indicia. *Mylan IPR*, Pap.27 (Jan. 9, 2024) (Conduct of the Proceeding); EX2002; EX2003.

Patent Owner has, for example, presented detailed objective indicia arguments in the Mylan IPR in response to Mylan’s three obviousness Grounds.³

³ While certain evidence related to commercial success was filed under seal, none of the expert declarations and evidence relating to unexpected results, industry praise, skepticism, or a long-felt and unmet need were redacted or filed under seal. See EX2001, 14, 16 (docket entries for declarations of Drs. Bakris, Goland, and

EX2004, 3. The '462 Patent's commercial embodiment is Ozempic®, and the evidence of objective indicia is extensive, covering the '462 and Ozempic®'s commercial success, unexpected results, skepticism, failure of others, long-felt but unmet need, and industry praise. EX2004, 3; EX2001, 12, 14, 16 (docket sheet entries for Declarations of Drs. Bakris, Goland, Blaha, Vellturo); EX2005, 2 ("I have been asked to provide my opinions regarding certain objective indicia of non-obviousness for the '462 patent."); EX2006, 2 (same); EX2007, 3 (same); EX2008, 5 ("I have been asked by [Patent Owner] to evaluate the commercial success of the drug Ozempic® and the extent to which Ozempic®'s commercial success is causally linked to the claims-at-issue from the ['462 Patent]...."). The corresponding proof involves testimony from five experts (Drs. Sinko, Goland, Blaha, Bakris, and Vellturo) and over 200 documentary exhibits. EX2001, 2, 4–16; EX2004, 3. Petitioner's rebuttal relies on four experts (Drs. Spiegel, Schwartzbard, Coca, and McDuff) and approximately 200 documentary exhibits. EX2001, 16–22.

In addition to objective indicia, the Mylan IPR also involves art subject to a swear-behind dispute. That same art is at issue here. Mylan and Apotex rely on

Sinko declarations of Bakris, Goland, Sinko); EX2005; EX2006; EX2009; EX2004.

WO421 for two of the five IPR Grounds. Pet.1, 5. So far in the Mylan IPR, the swear behind argument has involved the preparation and filing of four fact declarations, numerous exhibits, document production, two depositions of witnesses based overseas, and substantial factual development of the type not typically present in an IPR. EX2004, 2–3; EX2001, 14–15 (docket sheet entries for Declarations of Drs. Jensen, Flint, and Mses. Jiang and DiCicco).

III. Institution Should Be Denied Under §314(a)

The Board should deny institution of Apotex’s copycat Petition under §314(a) *General Plastic* because *Apotex’s Petition presents precisely the same art and arguments* as the instituted Mylan IPR, Petitioner *chose* not to seek timely joinder, and the *General Plastic* factors weigh in favor of discretionary denial. Apotex’s Petition is a copycat/“me-too” filing that is “assert[ing] the same unpatentability grounds” and is “*substantively identical* to Mylan’s petition” in the Mylan IPR. Pet.1. The Apotex Petition is *also untimely*: the deadline for seeking joinder passed nearly four months *before* Apotex filed the instant petition and its unauthorized joinder motion. §42.122(b) (“Any request for joinder *must be filed*, as a motion under §42.22, no later than one month after the institution date of any *inter partes* review for which joinder is requested.”); *see also Google Inc. v. Personalweb Techs., LLC*, IPR2014-00978, Pap.11, 4–5 (Oct. 30, 2014) (denying untimely motion for joinder filed one month after the statutory deadline in

§42.122(b)); *TrickleStar LLC v. Embertec Pty Ltd.*, IPR2017-00839, Pap.11, 32–33 (June 10, 2017) (denying joinder motion filed five days after deadline). And while the Board has, at times, considered whether a *timely* joinder motion was filed when analyzing *General Plastic*, there was none here. *Cf. Cent. Sec. Grp. – Nationwide, Inc. v. Ubiquitous Connectivity, LP*, IPR2019-01609, Pap.11, 8 (Feb. 26, 2020) (finding *General Plastic* “not particularly relevant” where a different petitioner files a copycat petition “in conjunction with a *timely* motion to join”).

Moreover, a §314(a) analysis is appropriate even if, *arguendo*, Petitioner were entitled to seek joinder: “*before* determining whether to join [copycat petitioner] as a party to the [] IPR, even though the Petition is a ‘me-too petition,’ [the Board] first determines whether application of the *General Plastic* factors warrants the exercise of discretion to deny the Petition under §314(a).” *See Apple Inc. v. Uniloc 2017 LLC*, IPR2020-00854, Pap.9, 5 (Oct. 28, 2020) (precedential); *T-Mobile USA, Inc. v. Voip-Pal.com, Inc.*, IPR2023-00638, Pap.11, 5–6 (July 28, 2023) (citing *Apple*, IPR2020-00854, Pap.9). The *General Plastic* factors weigh in favor of discretionary denial, and Petitioner’s late unauthorized joinder motion cannot change or avoid this analysis.

A. Discretionary Authority to Deny Under *General Plastic*

The Director has discretionary authority to institute or deny *inter partes* review, and has delegated that authority to the Board. §314(a); *see also* §42.4(a).

General Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Pap.19, 16 (Sept. 6, 2017) (precedential) (“*General Plastic*”), enumerates a non-exclusive list of factors the Director may consider and weigh to decide whether to institute under §314(a). But the *Consolidated Trial Practice Guide* also expressly contemplates that “additional factors that may bear on the Board’s discretionary decision” will “be considered along with the *General Plastic* factors”: “There may be other reasons besides the ‘follow-on’ petition context where the ‘effect... on the economy, the integrity of the patent system, the efficient administration of the Office and the ability of the Office to timely complete proceedings,’... includ[ing], for example, events in other proceedings related to the same patent, either ***at the Office***, in district courts, or the ITC.” USPTO, *Consolidated Trial Practice Guide* (Nov. 2019), at 58 (emphasis added) (quoting §316(b); citing *NetApp, Inc. v. Realtime Data LLC*, IPR2017-01195, Pap.9, 12–13 (Oct. 12, 2017)). One additional unenumerated factor contemplated for consideration is whether “the same or substantially the same prior art or arguments previously were presented to the Office”—a factor that, as detailed below, weighs in favor of discretionary denial. *General Plastic*, 19; *Samsung Elecs. Am., Inc. v. Uniloc 2017 LLC*, IPR2018-01756, Pap.9, 3 (May 28, 2019).

B. Institution Should Be Denied Because Petitioner Brings the Same or Substantially the Same Art or Arguments

Although the other *General Plastic* factors also favor denial here (*see infra*, §III.C), the Board may exercise its discretion to deny institution of Apotex’s Petition *solely* on the basis that Apotex raises the same art and arguments as in the previously-instituted Mylan IPR—indeed, the Board has found *far less* overlap sufficient for denial. *See Samsung*, IPR2018-01756, Pap.9, 3.

In *Samsung*, a first-time petitioner sought to challenge a patent for which several co-pending IPRs, brought by other parties, had already been instituted. IPR2018-01756, Pap.7, 23, 25 (Mar. 11, 2019). The petitioner was not a party to any of the previously-filed IPRs. And, while the new petitioner had not mirrored the previously-filed petitions, its petition included certain overlapping grounds and arguments from the earlier IPRs. *Id.* at 25. The Board determined that “most of the prior art and arguments advanced by Petitioner are the same as or substantially the same as the prior art and arguments advanced in the [earlier] IPRs,” and on that basis “exercise[d its] discretion to deny review under 35 U.S.C. §314(a)” in order “to preserve the Board’s resources.” *Id.* at 25–26, 30.

Subsequently, the petitioner sought rehearing, arguing the Board failed to provide a reasoned balancing of the *General Plastic* factors in favor of focusing exclusively on the similarity of the prior art and arguments from the previous IPRs. *Samsung*, IPR2018-01756, Pap.9, 3–4. The petitioner argued the Board erred in

denying the petition because it was petitioner’s first challenge—a factor purportedly weighing “particularly heavily in favor of institution”—while factors 2–5 were of little relevance and factor 6 was an unreasonable basis to outweigh the others. *Samsung*, IPR2018-01756, Pap.9, 3–4. The Board disagreed, explaining *General Plastic* itself “expressly contemplates that the similarity of prior art and arguments raised in a petition and follow-on petition are additional factors that can be considered ‘in the exercise of discretion under §314(a).’” *Id.* (quoting *General Plastic*, 19). The Board further explained that, even “[a]ssuming Petitioner is correct” and the only relevant factors to be considered were the petitioner’s first-time-filing status and petitioner bringing the same or substantially similar prior art, arguments, and grounds, the Board’s “[d]ecision does just that.” *Id.* at 5. “[T]he *General Plastic* factors... are not intended to represent *all* situations where it may be appropriate to deny a petition,” and analyzing “the cumulative nature of the prior art and arguments raised in the Petition and in the [previous IPRs] is consistent with” the Board’s discretionary denial framework. *Id.* at 7–8. Thus, the Board “disagree[d] that [it] erred in exercising [its] discretion to deny the Petition under 35 U.S.C. §314(a) because the Petition presented the same or substantially similar prior art and arguments already presented to the Board in the [previously filed petitions].” *Id.* at 12.

Here there is far more duplication than in the petition denied institution in *Samsung*. Petitioner here admits its Petition “is ***substantively identical*** to Mylan’s petition,” and “asserts the same unpatentability grounds....” Pet.1. Thus, unlike in *Samsung*, there is no question here about how much of the prior art or arguments are the same or substantially the same. The facts otherwise are very similar to those in *Samsung*, including because the *Samsung* petitioner had the benefit of that patentee’s preliminary response, the Board’s Institution Decision, and even patentee’s response to the prior petitions. *Samsung*, IPR2018-01756, Pap.7, 24–25. Here, too, Apotex had the benefit of PO’s POPR, the Institution Decision, and PO’s POR, and—if instituted for trial—is scheduled to have the benefit of PO’s Sur-reply and oral arguments and the Board’s final written decision in the Mylan IPR before any post-institution papers are due here.

Apotex’s belated filing of a late joinder motion and copycat petition does not change this analysis. *See Apple*, IPR2020-00854, Pap.9, 5; *T-Mobile USA*, IPR2023-00638, Pap.11, 5–6. Indeed, as with the *Samsung* petitioner, Apotex “could have requested [timely] joinder” or “filed its own petition that substantially differed from the petition filed in” the earlier IPR. *Samsung*, IPR2018-01756, Pap.9, at 11. Apotex didn’t, and institution should be denied. *Id.* Apotex’s Petition here would impose an unjustifiable burden on the Board and PO with none of the benefits or efficiencies that might generally be gained from timely copycat

petitions. Again, the Mylan IPR already includes 313 exhibits filed by Mylan and 328 exhibits filed by Patent Owner, with 13 experts (including 15 expert declarations so far), 8 fact witnesses (including the '462 inventor and a corroborating witness), numerous depositions (10 so far, with 6 additional depositions now scheduled), increased word counts for the parties, and two authorized schedule extensions to accommodate the unusually large record and discovery required. *Mylan IPR*, Pap.27 (Jan. 9, 2024) (Conduct of the Proceeding); EX2002; EX2003. Given the copycat nature of Apotex's Petition, the same issues, volume of evidence, and extensions are almost certain to be present here. The Board should thus exercise its discretion to deny the Petition under §314(a) because the Petition merely presents the same or substantially similar prior art and arguments already presented to the Board in the Mylan IPR particularly in view of the volume and complexity of the Mylan IPR. *See Samsung*, IPR2018-01756, Pap.7, 25–26; *Samsung*, IPR2018-01756, Pap.9, 5, 12. These issues will likely be resolved in the Mylan IPR later this year, not long after the institution decision for this IPR.

C. Institution Should Also Be Denied Because the Remaining *General Plastic* Factors Weigh in Favor of Denial

As noted above, the Board need not reach the expressly-enumerated *General Plastic* factors to deny institution here. *See Samsung*, IPR2018-01756, Pap.9, 5, 12. Nonetheless, the enumerated *General Plastic* factors considered as a group, as

well as other additional factors, also weigh in favor of discretionary denial. *See, e.g., 3M Co. v. Bay Materials, LLC*, IPR2023-00243, Pap.8, 11 (July 7, 2023) (denying institution under *General Plastic* for challenges to the same claims in multiple, staggered petitions).

1. Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent

Factor 1 considers whether Apotex or a party with whom Apotex has a significant relationship previously filed a petition directed to the same claims of the same patent. *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Pap.10, 10 (May 1, 2019) (precedential). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]. See *Apple*,
IPR2020-00854, Pap.9, 9, 11 (finding petitioner’s “lack of explanation” for certain
factors (2, 4, and 5) weighed in favor of denial for those factors)).

Even if it were assumed, *arguendo*, that Petitioner had no relationship at all
with Mylan, DRL, or Sun, this factor would be entitled to little weight (and
discretionary denial would nevertheless be appropriate) because of the ***complete
overlap*** of the Grounds in this IPR and the Mylan IPR. Pet.5; *Samsung Elecs. Co.
v. Elm 3DS Innovations, LLC*, IPR2017-01305, Pap.11, 19 (Oct. 17, 2017) (“[T]he
high degree of similarity of Samsung’s instant Petition with the prior petitions by
Petitioners..., as discussed above, reduces the weight we accord this factor.”);
Nichia Corp. v. Document Sec Sys., Inc., IPR2018-01167, Pap.10, 19, 25 (Nov. 30,
2018) (exercising discretion to deny, finding factor 1 “weighs minimally against”
denying institution where “the instant Petition uses the prior art asserted in the
[prior] Petition... [and] in the same manner” and that “degree of similarity”
between the two “reduces the weight [the Board] accord[s] this factor”); *United*

⁴ [REDACTED]
[REDACTED]

Fire Prot. Corp. v. Engineered Corrosion Sols., LLC, IPR2018-00991, Pap.10, 12–13, 17–18 (Nov. 15, 2018) (exercising discretion to deny, finding factor 1 weighed only “moderately against exercising... discretion to deny institution” given “the Petition presents many issues and arguments” that are present in a prior IPR and “is directed to the same claims of the same patent as the [prior] IPR petition”); *see also Unified Pats. Inc. v. Finjan, Inc.*, IPR2019-01611, Pap.18, 12 (April 13, 2020) (“We agree with Patent Owner that the similarity of the set of challenged claims, which has been repeated over multiple petitions for *inter partes* review, weighs in favor of a discretionary denial. But this is counterbalanced by the fact that Petitioner is not ‘the same petitioner’ who filed such prior petitions. Accordingly, we treat this factor as **neutral** in our weighing of the *General Plastic* factors.”). And while Petitioner does not literally use the same experts as Mylan, the fact that Petitioner filed the Mylan declarations (EX1003, EX1005, EX1007) and Petitioner’s experts “adopt[] the opinions set forth by [the experts] in connection with the Mylan IPR” with largely verbatim declarations further reduces the weight that this factor should be accorded. Pet.5; EX1501, ¶1 (“I agree with Dr. Bantle’s opinions set forth in his declaration, so I have adopted them.”); EX1503 (“I agree with Dr. Jusko’s opinions set forth in his declaration, so I have adopted them.”), ¶1; EX1505, ¶1 (“I agree with Dr. Dalby’s opinions set forth in his declaration, so I have adopted them.”); *cf. Elm 3DS*, IPR2017-01305, Pap.11, 19 (“Petitioner’s use

of the same expert... in this Petition as used to support the reasoning in prior petitions further reduces the weight we accord this factor.... [W]e conclude [factor 1] weighs minimally against exercising our discretion.”); *compare* EX1003 with EX1501; *compare* EX1005 with EX1503; *compare* EX1007 with EX1505.

2. *Factor 2: whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it*

“The relevant issue under factor 2 is... whether the prior art references relied on in the follow-on petitions... could have been found with reasonable diligence” at the time the first petition was filed. *General Plastic*, 19–20. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁵ PO acknowledges that *General Plastic* factors 2–5 may not be considered since Apotex itself is a first-time petitioner. However, consideration of factors 2–5 here is warranted given the unusual circumstance of this untimely copycat Petition.

Petitioner knew or should have known of most of the art in its Petition at least as of the time it learned of the '462 itself, and of all of the art by the time it learned of the Mylan IPR. In instituting the Mylan IPR, the Board found Mylan's petition "on the whole" raised "the same art and arguments previously before the Office" during the prosecution of the '462 Patent. *Mylan IPR*, Pap.10, 13 (Oct. 4, 2023). The same is therefore true here with Petitioner's copycat petition. Indeed, the Petition art includes art that was presented during prosecution or is cumulative of art that was presented during prosecution (all art for Grounds 1, 2 and 4, and the primary reference for Grounds 3 and 5). *Mylan IPR*, Pap.10, 13 (Oct. 4, 2023) (determining Lovshin (EX1012) is cumulative of WO421 (EX1011) because both references are offered for the same teachings). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, Petitioner likely knew or should have known of this art whenever it became aware of the '462 Patent (and before the Mylan IPR's institution), including because much of the art was cited or are cumulative of art cited on the face of the '462 Patent itself. As to the *secondary* references that were not presented during prosecution (Grounds 3 and 5's '424

Publication and Ground 5's NCT773), a reasonable search would have uncovered these references, as evidenced by their inclusion in the Mylan IPR. Further, Petitioner indisputably had access to all the art Mylan presented in the Mylan IPR and which Petitioner re-presents to the Office here by the time Petitioner learned of the Mylan IPR, though Petitioner again elected to omit that specific date from its Petition.

Regardless of how long before the Mylan IPR institution Petitioner knew or should have known of the art in this Petition, Factor 2 of *General Plastic* weighs in favor of exercising discretion to deny based on Apotex's knowledge at the time of institution in the Mylan IPR. *See Expedia, Inc. v. Int'l Bus. Machs. Corp.*, IPR2018-01459, Pap.7, 29 (Jan. 29, 2019) ("As to Factor 2, as Patent Owner points out, Levergood is cited on the face of the '601 patent. Thus, Petitioner was or should have been aware of Levergood.... Thus, Factor 2 weighs in favor of denial."); *3M*, IPR2023-00243, Pap.8, 6, 8–9 (finding factor 2 "favors denial of institution" where PO's uncontested evidence of when petitioner knew or should have known of art, including that some art was cited on the face of the patent, and therefore was known since the prior petition, which was filed five months prior to the instant petition); *Finjan*, IPR2019-01611, Pap.18, 13 (finding petitioner brought the same grounds as in an earlier petitioner's proceeding and thus had

access to the art in the prior public petition or could have found it through reasonable diligence).

3. ***Factor 3: whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition***

“[F]actor 3 is directed to Petitioner’s potential benefit from receiving and having the opportunity to study Patent Owner’s Preliminary Response, as well as our institution decisions on the first-filed petitions....” *General Plastic*, 17; *3M*, IPR2023-00243, Pap.8, 9 (finding factor 3 favors denial given “that Petitioner had the opportunity” to “craft arguments in the instant Petition based on positions presented in the Preliminary Response” recognizing “‘the potential for abuse’ in situations like this one”). Petitioner filed the instant petition on March 1, 2024 (Pet.69), nearly ***eight months after PO’s July 6, 2023 preliminary response*** in the Mylan IPR was made available (EX2001, 3), nearly ***five months after receiving the Board’s decision to institute*** (*Mylan IPR*, Pap.10 (Oct. 4, 2023)), and ***nearly two (2) months after receiving the POR*** in the Mylan IPR (EX2004).

In sum, Petitioner’s admissions and the timing of events here show Petitioner was tracking and had access to PO’s Preliminary Response, the Board’s Institution Decision, and even PO’s POR before it filed its untimely Petition and joinder motion. And importantly, if instituted, Apotex will perpetually and improperly benefit (to PO’s prejudice) from its own gamesmanship, and will have

continued opportunities to roadmap its arguments based on the developments (and even the final written decision) in the Mylan IPR. Thus, to the extent this factor is considered (*see n.6*), the third *General Plastic* factor “weighs in favor of discretionary denial.” *Sonos, Inc. v. Google LLC*, IPR2023-01284, Pap.10, 9–10 (Mar. 8, 2024) (finding factor 3 weighed in favor of discretionary denial where petitioner had received preliminary response, institution decision, and POR before filing petition); *Apple*, IPR2020-00854, Pap.9, 10 (finding factor 3 weighs in favor of denying institution given petitioner “had access to a Board Decision or a preliminary response”).

4. *Factor 4: the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition*

The Petition does not address when Apotex learned of the prior art it cited. But, as discussed above (*supra* §III.C.2), Apotex admits it was monitoring the ’462 Patent and the Mylan IPR at least as of the October 4, 2023 institution decision (EX1507, ¶12). Thus Apotex waited at minimum five months between learning of the art at institution and recycling the art in its copy-paste Petition, though this likely underestimates Apotex’s delay in filing the petition after learning of the art. Pet.1, 5; *supra* §III.C.2.

In light of these circumstances, *General Plastic* factor 4 weighs in favor of discretionary denial. *Valve*, IPR2019-00062, 11, 14–15 (“The fact that Valve

waited five months after HTC’s petition to file the Petition in this case favors denying institution” with respect to factor 4 where petition includes references petitioner knew and references petitioner “could have found[] through the exercise of reasonable diligence around the time of HTC’s petition.”); *3M*, IPR2023-00243, Pap.8, 10 (“Petitioner provides ‘no explanation of its decision to wait’ nearly five months to [file]. An inadequately explained delay of similar length supported denial of institution in *Valve*, even where a different petitioner filed the second petition. Both the length of the delay (factor 4) and Petitioner’s failure to explain the delay (factor 5) favor denying institution.”); *see also Intel Corp. v. Inst. of Microelecs., Chinese Acad. of Scis.*, IPR2019-00834, Pap.14, 10–11 (June 19, 2020) (finding eleven month delay “warrant[s] a conclusion that the fourth *General Plastic* factor weighs in favor of denying institution”).

5. *Factor 5: whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent*

To the extent this factor is considered, Petitioner’s explanation for its delay in filing a copy-cat petition from the time it knew or should have known of the art (at minimum the five-month delay between the institution of Mylan’s IPR and filing of the present petition) is wholly inadequate. *Ivantis, Inc. v. Glaukos Corp.*, IPR2019-00972, Pap.7, 16 (Oct. 10, 2019) (“Without providing an adequate explanation as to why Petitioner could not have raised these challenges earlier,

there appears to be no justification in permitting Petitioner to wait to file its Petition until after it has had the advantage of seeing the 1147 IPR preliminary response and the 1147 IPR decision. Consequently, this factor also weighs against institution.”). Apotex has offered no sufficient explanation for delaying as long as it did *simply to copy Mylan’s petition and supporting declarations*, particularly given that Apotex violated the one-month time limit—helping itself to more than 4 additional months—and where two copycat petitioners managed to timely file. *See Longi Green Energy Tech. Co. v. Hanwa Sols. Corp.*, IPR2020-00047, Pap.18, 11–12 (Apr. 27, 2020) (denying institution under *General Plastic*, finding with respect to factor 5 that similarity of petitions “suggests that it should have taken Petitioner less time to prepare the present Petition than it otherwise would have if Petitioner had needed to analyze entirely different claims and references in the present Petition”); EX1507, ¶2; *see also 3M*, IPR2023-00243, Pap.8, 10 (finding factor 5 favors denying institution given “[a]n inadequately explained delay of similar length,” nearly five months, “supported denial of institution in *Valve*, even where a different petitioner filed the second petition”).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

General Plastic factor 5 weighs in favor of discretionary denial. *3M*, IPR2023-00243, Pap.8, 10; *Sonos*, IPR2023-01284, Pap.10, 11.⁶

6. Factor 6: the finite resources of the Board

Particularly given the voluminous evidence that the Board must already review for the Mylan IPR (*see supra* §II.B) and the likelihood that the record here will be equally voluminous if Apotex is permitted to re-enact Mylan’s entire IPR

⁶ Although not the case here, even if factors 2–5 had been neutral, the *General Plastic* analysis would still favor discretionary denial based on the other factors. *See Samsung*, IPR2018-01756, Pap.9, 5 n.8 (denying institution based on *General Plastic* without weighing factors 2–5, which it found not relevant).

proceeding with the unfair roadmapping benefits of hindsight nearly 12 months later (with trial beginning in September 2024 vs. October 2023),⁷ Petitioner's untimely copycat petition would require the Board to duplicate its analysis of this extensive record, severely imposing upon the finite resources of the Board. *Longi Green Energy Tech.*, IPR2020-00047, Pap.18, 12. That the Petition is a copycat is not relevant, as its joinder motion was untimely and Petitioner is not entitled to join, consolidate, or coordinate this IPR with the Mylan IPR. Pap.9. Petitioner's delay thus would involve a second separate proceeding were the Board to institute Apotex's Petition. *See NetApp Inc. v. Realtime Data LLC*, IPR2017-01195, Pap.9, 12-13 (Oct. 12, 2017) (exercising discretion to deny institution where petitioner's delay prevented the Board from joining, consolidating, or coordinating the proceedings with "earlier-filed proceedings involving the same patent" such that

⁷ Indeed, the institution decision here is due by September 12, 2024, but the final written decision in the Mylan IPR could come as soon as approximately October 4, 2024 or shortly thereafter, as we understand is the Board's practice in the case of joinder. In any case, a decision in the Mylan IPR is likely to issue before any or at least most of any post-institution briefing would be due in this IPR, and Apotex would have the benefit of a final written decision in the Mylan IPR on the same grounds it raises in its petition throughout the duration of the proceedings.

instituting an IPR “at this time would require the Board to conduct an entirely separate proceeding involving numerous issues that have been considered already, and likely will be resolved,” and “[t]he result would be a significant waste of the Board’s resources”); *Ivantis*, IPR2019-00972, Pap.7, 17 (“In general, having multiple petitions challenging the same patent, especially when not filed at or around the same time, as in this case, is inefficient and tends to waste resources.”); *see also* Pap.9, 9–11.

Moreover, given Apotex’s failure to file a timely joinder motion, this Petition effectively presents “multiple, staggered petitions challenging the same patent and same claims,” which the Board has said it views “[a]s a general rule” to be “unfair to patent owners and... an inefficient use of the *inter partes* review process.” *3M*, IPR2023-00243, Pap.8, 10–11. “Going forward on the instant Petition ‘would be an inefficient use of the Board’s resources’” where Petitioner reasonably could have raised these grounds in an earlier, and therefore timely, copycat petition, or brought a petition presenting art and arguments that are different from the previously-filed petitions. *Id.* Thus, the sixth *General Plastic* factor weighs in favor of denying institution of the proceeding. *3M*, IPR2023-00243, Pap.8, 10; *Apple*, IPR2020-00854, Pap.9, 12.

7. *Factor 7: the requirement under 35 U.S.C. §316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review*

For the same reasons discussed for factor 6, Petitioner’s untimely copycat presents “multiple, staggered petitions that challenge the same patent claims” and therefore “the requirement that the Board issue a ruling within one year of institution” favors denial of institution. *3M*, IPR2023-00243, Pap.8, 10. This is particularly so in view of the volume and complexity of evidence and issues in the Mylan IPR (including the number of exhibits, witnesses, depositions, and volume of briefing), which PO expects would be similar in volume and complexity in this IPR. *See NetApp*, IPR2017-01195, Pap.9, 12–13; *Longi Green Energy Tech.*, IPR2020-00047, Pap.18, 12 (noting “because of Petitioner’s five-month delay, it would be difficult, if not impossible, for the Board to adjust due dates in the... IPR enough to coordinate with the present proceeding, and still meet the statutory mandate to issue a final written decision.... Accordingly, [factors 6 and 7] weigh in favor of invoking our discretion to deny institution”). To accommodate the scheduling of depositions, and in view of the volume of materials and complexity of the proceedings, the schedule—including deadlines that may not be amended without the Board’s permission—has been amended twice. EX2002; EX2003. At

this point, oral argument is just six weeks prior to the original 1-year deadline,⁸ which may result in the final written decision deadline being extended. EX2003, 2. The same very well may be necessary here given the anticipated volume and complexity of the record and arguments. Pet.1. Thus, factor 7 weighs against institution. 3M, IPR2023-00243, Pap.8, 10.

IV. Petitioner Fails to Address Objective Evidence of Non-Obviousness

Even if, *arguendo*, the Board decides not to exercise its discretion to deny institution under §314(a), Petitioner has not addressed the objective evidence of non-obviousness that Apotex was clearly aware of from public materials in the Mylan IPR that Apotex has been monitoring. Pet.59; EX2004, 3. Objective indicia of non-obviousness are “not just a cumulative or confirmatory part of the obviousness calculus”—they “**must** be considered.” *See Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). The Board has denied institution of asserted obviousness grounds when evidence of such objective indicia is presented, and the Board has taken a particularly dim view of petitioners who choose not to deal with known objective indicia of non-

⁸ The Board indicated it was likely to schedule oral argument for the week of August 26, 2024.

obviousness. *See Merck Sharp & Dohme Corp v. Genentech, Inc.*, PGR2021-00039, Pap.10, 31, 35–39 (July 24, 2021) (denying institution, noting Petitioner’s inadequate evidence to overcome PO’s surprising results, industry praise, unexpected synergy, and other objective evidence, explaining “[n]one of this additional evidence is adequately addressed... underscor[ing] [the Board’s] determination that Petitioner has not shown that it is more likely than not that it would prevail”); *Dish Network LLC v. Sound View Innovations, LLC*, IPR2020-00969, Pap.20, 29–33 (Nov. 25, 2020) (finding “Petitioner’s obviousness arguments... are outweighed,” noting “[i]ndustry praise provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected the claimed invention” and the Board “heed[s] the Federal Circuit’s guidance that such evidence ‘can be the most probative evidence of non-obviousness in the record, and enables the court to avert the trap of hindsight’” (quotation omitted)); *Stryker Corp. v. KFX Med., LLC*, IPR2019-00817, Pap.10, 28–29 (Sept. 16, 2019) (“Despite knowing of the Arthrex litigation,” which included secondary considerations evidence, “Petitioner did not address the secondary considerations evidence in its Petition. We have cautioned petitioners in prior proceedings that petitions may be denied if they do not address known evidence of secondary considerations.... Petitioner’s failure to address the known evidence of secondary considerations further weighs in favor of denying

institution.”); *Merial Ltd. v. Virbac*, IPR2014-01279, Pap.13, 27, 29 (Jan. 22, 2015) (denying institution, “Merial was aware of the unexpected results” and thus “Merial should have addressed unexpected results in the first instance”); *Lupin Ltd. v. Vertex Pharms. Inc.*, IPR2015-00405, Pap.13, 21–23, 26–27 (July 9, 2015) (acknowledging “array of objective evidence Patent Owner puts forward in support of the nonobviousness of the challenged claims” and finding Petitioner has not persuaded the Board it would prevail on certain claims).

At the time it filed its Petition, Petitioner here was indisputably aware of the large body of evidence showing objective indicia of non-obviousness that cut against its argument that the challenged claims are unpatentable under §103. The POR in the Mylan IPR sets forth in great detail objective evidence of non-obviousness of the remarkably successful, world-renowned type-2 diabetes (“T2D”) treatment, Ozempic[®]. EX2004, 3. The POR provides evidence of, *inter alia*, Ozempic[®]’s “immense commercial success,” the unexpected results relating to HbA_{1c} reduction, weight loss, cardiovascular risk reduction, and improvements in chronic kidney disease in T2D patients using Ozempic[®], and the industry praise that has led Ozempic[®] to become a household name. *Id.*

But Petitioner simply chose to not address these material facts in its Petition. This failure is a sufficient basis to deny institution, as Apotex’s obviousness

grounds constitute the majority of the Petition’s grounds and challenged claims.⁹

See Deeper, UAB v. Vexilar, Inc., IPR2018-01310, Pap.7, 41–43 (Jan. 24, 2019)

(informative) (denying institution where “Petitioner demonstrate[d] a reasonable likelihood of prevailing with respect to only two claims on one asserted ground”);

Amazon.com, Inc. v. VB Assets, LLC, IPR2020-01374, Pap.10, 36 (Feb. 4, 2021)

(“Petitioner fails to demonstrate a likelihood of prevailing with respect to its challenge to 31 of these claims. Thus, were we to institute review, the resulting trial would go forward on all 35 claim challenges although we find only four claim challenges demonstrate a reasonable likelihood of prevailing. We find that instituting trial, therefore, would not be an efficient use of the Board’s time and resources. Consequently, we exercise our discretion to deny institution of the entire Petition under 35 U.S.C. §314.”).

V. Conclusion

Petitioner requests that the Board deny institution under §314(a) and *General Plastic*, and because Petitioner failed to address the objective evidence of non-obviousness of which it was aware.

⁹ Apotex’s obviousness grounds here cover all 10 claims, whereas its two anticipation grounds cover only claims 1–3. Pet.5.

Respectfully submitted,

Dated: June 12, 2024

By: /Megan Raymond/

PAGE COUNT CERTIFICATE

The undersigned certifies that the foregoing PATENT OWNER'S PRELIMINARY RESPONSE UNDER 37 C.F.R. §42.107 complies with the type-volume limitation in 37 C.F.R. §42.24(c)(1). According to the word-processing system's word count, the brief contains 6,649 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a)(1).

Dated: June 12, 2024

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER'S
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