

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

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

LIST OF EXHIBITS

Exhibit	Description
EX2001	Excerpt of Defendants’ Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2002	Petition for <i>Inter Partes</i> Review, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.1 (Mar. 16, 2023)
EX2003	Declaration of Sayem Osman
EX2004	Stipulation and Order Regarding Trial of the MPI Ozempic Litigation, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 245 (D. Del. Oct. 31, 2023)
EX2005	Nov. 29, 2023 Email from E. Goldschlager to Counsel, re: IPR2023-00724 – Request for Conference Call
EX2006	Scheduling Order, <i>Novo Nordisk Inc. v. Rio Biopharms., Inc.</i> , No. 1:22-cv-00294-CFC, Dkt. 22 (D. Del.)
EX2007	Excerpt of Transcript of Dec. 13, 2023 Claim Construction Hearing, <i>Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.</i> , No. 23-101-CFC (D. Del. Dec. 13, 2023)
EX2008	Claim Construction Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 148 (D. Del. July 25, 2023)
EX2009	Joint Stipulation and Order Amending Scheduling Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , MDL No. 22-MD-03038-CFC, Dkt. 268 (D. Del. Dec. 1, 2023)
EX2010	Excerpt of Novo Nordisk’s Second Amended Disclosures to Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc., <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. July 28, 2023)
EX2011	U.S. Patent No. 8,114,833
EX2012	Waiver of Service of Summons for Dr. Reddy’s Laboratories, Inc., <i>Novo Nordisk Inc. v. Dr. Reddy’s Lab ’ys Ltd.</i> , No. 1:22-cv-00298-CFC, Dkt. 6 (D. Del., Mar. 4, 2022)
EX2013	Waiver of Service of Summons for Dr. Reddy’s Laboratories Ltd., <i>Novo Nordisk Inc. v. Dr. Reddy’s Lab ’ys Ltd.</i> , No. 1:22-cv-00298-CFC, Dkt. 7 (D. Del. Mar. 4, 2022)

Exhibit	Description
EX2014	Excerpt of Redacted Patent Owner's Response, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.30 (Jan. 17, 2023)
EX2015	Excerpt of Novo Nordisk's Initial Responses to Defendants' Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Dec. 21, 2022)
EX2016	Transfer Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 1 (D. Del. Aug. 5, 2022)
EX2017	INTENTIONALLY OMITTED
EX2018	Excerpt of Defendants' Supplemental Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Nov. 2, 2023)
EX2019	Novo Nordisk Production Letter, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 17, 2023) [REDACTED]
EX2020	Compilation of Defendants' Production Letters, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.) [REDACTED]
EX2021	Compilation of Rule 30(b)(1) Deposition Notices, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
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I. Introduction

As detailed in this §42.107¹ Preliminary Response by Patent Owner Novo Nordisk A/S (“PO”), the extensively- and consciously-delayed Petition in this matter (“Petition”/“Pet.”) should be denied under the Board’s §314(a) discretion, and because it was not “properly filed” under §315(c).

Petitioners Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. (collectively, “Petitioner”) filed the present IPR challenging the validity of U.S. Patent No. 10,335,462 (“’462”) ***eighteen months*** after they were sued for infringing the ’462, seeking to join the pending *inter partes* review proceedings in *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 (the “Mylan IPR”)—proceedings Petitioner had, until then, been watching from the sidelines. Petitioner’s Motion for Joinder confirmed that Petitioner’s request to participate would only affect these proceedings if (timely) petitioner Mylan settled and were terminated from the Mylan IPR: “DRL will assume a ‘silent understudy’ role and will not take an active role in the inter partes review proceeding unless, the Mylan Petitioner ceases to participate in the instituted IPR.” Pap.3, 2.

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

Petitioner, along with Mylan, Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (which filed a subsequent copycat petition, IPR2024-00107), and several other defendants who have not filed IPRs (*e.g.*, Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Limited, and Rio Biopharmaceuticals, Inc.), have also challenged the validity of '462 in parallel Hatch-Waxman litigation that is currently pending in the District of Delaware as *In re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del.) (consolidated case) (the “Delaware Litigation” or “parallel litigation”).² EX2001, 33-34. While Petitioner has watched the Mylan IPR move forward, Delaware Litigation claim construction has been completed, fact discovery has closed, and the district court has continued to move toward trial eight months from now.

The circumstances here support denial under §314(a) based on the factors laid out in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Pap.11 (Mar. 20, 2020) (“*Fintiv*”) (precedential). In evaluating the *Fintiv* factors, “the Board takes a

² The Delaware Litigation is a consolidated case involving several defendant groups. The case against Petitioner is individually captioned as *Novo Nordisk Inc. and Novo Nordisk A/S v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, C.A. No. 22-298-CFC.

holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* at 6. The Office, based on its experience administering the AIA, “has recognized the potential for inefficiency and gamesmanship in AIA proceedings, given the existence of parallel proceedings between the Office and district courts.” USPTO, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, at 1 (June 21, 2022) (hereinafter *USPTO Interim Procedure for Discretionary Denials*). The Office designated *Fintiv* as precedential to “minimize potential conflict between the [PTAB] and district court proceedings,” and thereby “mitigate[] concerns of potentially conflicting decisions and duplicative efforts between the district court and the PTAB.” *Id.* at 1, 7. And in refining its approach to the *Fintiv* analysis in June 2022, the Office reiterated the importance of efficiency and limiting unnecessary and counterproductive litigation costs while improving patent quality—including by “avoid[ing] inconsistent outcomes between the PTAB and the district court....” *Id.* at 1, 7-8.

In the parallel litigation here, which is *far-advanced*, Petitioner is already actively litigating *almost all of the IPR art* (compare Pet.22, 27-29, 36-37, 54-55 with EX2018, 6-38) *including two of the three weak obviousness combinations* that Petitioner advances here. The parallel litigation is scheduled to start trial on September 30, 2024—*before* even the current final written decision date of the

Mylan IPR and certainly *before* any resulting extension of that final written decision date if this Petition is instituted and joined to the Mylan IPR (a step that would remove any statutory final-written-decision deadline). Had Petitioner wished to make arguments about '462's validity before the Board, it could have filed an IPR long ago. Having chosen not to do so, and to proceed, instead, through litigation in the district court, Petitioner should not now be permitted to foist onto the parties, the Board, and the district court the burdens and inevitable waste of resources its much-delayed duplicative Petition would entail upon any departure of Mylan from its own IPR. *The only impact of this Petition* and Petitioner's presence in a joined IPR would be to continue proceedings if Mylan (the only *timely* petitioner under §315) were dismissed. *E.g.*, Pap.3, 2 (Petitioner "will not take an active role... unless the Mylan Petitioner ceases to participate"). And Petitioner's choice to *delay* its own challenge before the Office—and its attendant request for joinder, *eliminating any final-written-decision deadline*—significantly increases the risk of inconsistent outcomes in close proximity in two different jurisdictions. *Cf., e.g., USPTO Interim Procedure for Discretionary Denials*, 7-8. PO respectfully requests that institution be denied.

II. *Fintiv* Is Appropriate and Necessary to Consider Before Institution

Although this is a copycat Petition, the Board nevertheless must first consider whether institution of this Petition is warranted, including with respect to

discretionary denial, before addressing joinder. *LG Elecs., Inc. v. Ancora Techs., Inc.*, IPR2021-00581, Pap.16, 6, 11-12 (June 10, 2021) (denying institution of copycat petition based on *Fintiv* pursuant to §314(a), noting “before determining whether to join [copycat petitioner] as a party to the [] IPR, we first determine whether the petition warrants institution under § 314(a)”); *see also Facebook, Inc. v. Windy City Innov., LLC*, 973 F.3d 1321, 1332 (Fed. Cir. 2020) (“[T]he joinder decision is a separate and subsequent decision to the institution decision.”); *Apple Inc. v. Uniloc 2017 LLC*, IPR2020-00854, Pap.9, 4-5 (Oct. 28, 2020) (precedential) (denying copycat petition based on Director’s discretionary authority and *General Plastic*, noting “the discretion of the Director to join a party to an ongoing IPR is premised on the Director’s determination that the petition warrants institution... before determining whether to join Apple as a party... we first determine whether the application of the *General Plastic* factors warrants the exercise of discretion to deny the Petition under 314(a).”).

III. This is PO’s First Genuine Opportunity to Brief *Fintiv* in Connection with Petitioner’s Delaware Litigation

Although Mylan is also party to the Delaware trial, the fact that the Mylan IPR was instituted without any *Fintiv* dispute is irrelevant here. At the time of the October 4, 2023 institution decision date for the Mylan IPR (and the October 6, 2023 expected institution date based on the date PO filed its POPR in the Mylan IPR), *Mylan did not yet have a trial date*. Mylan IPR, Paper 5, 1; *id.*, Paper 1, 65-

66. PO's parallel litigation with Mylan was a separate case, venued in the Northern District of West Virginia, and had been consolidated with the Delaware Litigation as a multidistrict litigation case for pre-trial proceedings only. The Mylan litigation was then to be remanded to West Virginia for trial, with trial expected after the Delaware trial, but with no indication of exactly when that later trial would be scheduled. EX2016, 4 (transferring and consolidating in the District of Delaware all pretrial proceedings before jurisdiction is returned to the Northern District of West Virginia); EX2006, 38 (Delaware Litigation "Pretrial Conference" scheduled for September 19, 2024); EX2009, 4 ("No other deadlines set forth in the Scheduling Order are altered by way of this stipulation."). Indeed, Mylan affirmatively argued as much to avoid discretionary denial of its own petition. EX2002, 65-66 (arguing "Petitioner [Mylan]'s trial is *likely to be even later*" than September 30, 2024). Accordingly, given the particular circumstances in the Mylan IPR (including that there was no joinder pending), PO did not argue for discretionary denial of that IPR under *Fintiv*.³ The circumstances here are

³ Mylan is only a party to the Delaware Litigation trial now because, on October 31, 2023, *after* the institution decision in the Mylan IPR, Mylan stipulated to proceeding with trial together with Petitioner in the September 30, 2024 Delaware trial. EX2004, 3. Had Mylan stipulated to join the Delaware Litigation trial one

different including because, at the time of *this* POPR, there is a trial date on '462 validity scheduled before the expected final written decision date, even on the Mylan petition, and Petitioner's request for institution and joinder (whose sole impact would be to allow Petitioner to continue active proceedings if Mylan is *dismissed*) would mean there is *no* deadline for a final written decision.

§316(a)(11). As detailed in the next section, here, the *Fintiv* factors weigh heavily against institution.

IV. Institution Should Be Denied Under 35 U.S.C. §314(a)

A. The Parallel Litigation Will Not Be Stayed (Factor 1)

It is highly unlikely the Delaware Litigation will be stayed. No stay of the Delaware Litigation has been sought or granted. Patent Owner does not intend to ask for a stay. Nor has Petitioner indicated any plans to seek a stay (which would be a highly unusual request by a defendant in an ANDA case) or suggested the Court would grant one. Further, as discussed below, the trial is set only five months after the institution decision here is due, and the case is in its late stages, with fact discovery complete and expert discovery expected to be almost complete

month earlier, PO would have been able to timely argue that institution should be denied based on *Fintiv*. PO's request to brief this issue after institution in the Mylan IPR was denied. EX2005.

by the time the institution decision here is due. *Infra*, §VI.C. Further, stays are particularly discouraged in ANDA cases due to prejudice. *See, e.g., In re Brimonidine Pat. Litig.*, No. 07-MD-1866 GMS, 2008 WL 4809037, at *2 (D. Del. Nov. 3, 2008) (denying motion for stay, finding defendant would “be unduly prejudiced if this action were stayed” because, in part, “staying this action against [defendant] will delay market entry of any [defendant] generic product covered by the ANDA at issue in this litigation,” a consequence that is “not insignificant”). And it is further unlikely that the Court would stay the Delaware Litigation given the advanced status of the case. *See Astellas US LLC v. Apotex Inc.*, No. 1:18-cv-1675-CFC-CJB, 2021 WL 9031821, at *2 (D. Del. Feb. 19, 2021) (denying motion to stay in ANDA case and stating, “the status of this case is undoubtedly well advanced, which weighs against a stay.... [E]xpert discovery is set to close in April of this year. And trial is set to happen soon, in June 2021. Absent a really good reason to do otherwise, when a case gets this close to trial and the Court and the parties have put this much effort into the litigation, the case is not normally stayed.”); *see also Fintiv*, Pap.11, 5-6; *infra*, §IV.C (*Fintiv* Factor 3). Therefore, this factor favors denial of institution. *Mylan Lab ’ys Ltd v. Janssen Pharms.*, IPR2020-00440, Pap.17, 13-14 (Sept. 16, 2020) (finding stay of parallel litigations unlikely in view of, *e.g.*, 30-month 355(j)(5)(B)(iii) limit and advanced stage of litigation); *Google LLC v. Uniloc 2017 LLC*, IPR2020-00115, Pap.8, 4 (Mar. 27,

2020) (finding factor 1 “weigh[s] in favor of denying institution,” noting “[t]here is no evidence that the district court has granted (or would grant) a stay pending *inter partes* review”).

B. Even if Mylan’s Final Written Decision Date Were Considered, the Parallel Litigation Trial Date Precedes It; and No Final Written Decision Date Will Apply if This Petition is Instituted and Joinder is Granted (Factor 2)

If this Petition is instituted and joinder is granted, the Board will have no deadline to issue its final written decision. §316(a)(11); §42.100(c). Moreover, Petitioner itself has made clear that its Petition and joinder request have an impact here *only if trial on Mylan’s petition is terminated and Mylan is no longer a party* (DRL IPR, Pap.3, 2)—further underscoring the meaninglessness of looking to Mylan’s final written decision date as a point of comparison. *Cf. Apple v. Uniloc*, IPR2020-00854, Pap.9, 4, 8, 11-12 (considering impact on IPR if copycat petitioner is joined and original petitioner settles in the context of *General Plastic* §314(a) analysis, noting institution and joinder would allow copycat petitioner to continue an otherwise terminated proceeding and use Board resources). Nonetheless, even if it is considered, the Delaware trial precedes Mylan’s current final written decision deadline.

The Delaware trial is currently scheduled on September 30, 2024. EX2006, 38; EX2009, 4; *Samsung Elecs. Co. v. Ancora Techs., Inc.*, IPR2020-01184, Pap.11, 11-12 (Jan 5, 2021) (noting Board focuses on trial date and “do[es] not

speculate as to the schedule for post-trial motions”). The final written decision in the Mylan IPR (before joinder) is due October 4, 2024. IPR2023-00724, Pap.11 (Oct. 4, 2023). Thus, even if Mylan IPR’s final written decision date were considered, the Delaware Litigation will start trial before a final written decision regarding ’462 validity is expected to issue. *E.g., ResMed Corp. v. Cleveland Med. Devices Inc.*, IPR2023-00565, Pap.13, 11 (Sept. 25, 2023) (finding *Fintiv* factor 2 “weighs in favor of exercising discretion to deny institution” where the “**trial date** in the [] district court is set for **one month before a final decision is due** in this case”). Petitioner has presented no other evidence regarding trial dates, and the Board “generally take[s] courts’ trial schedules at face value absent some strong evidence to the contrary.” *See Samsung v. Ancora*, IPR2020-01184, Pap.11, 21; *ResMed Corp.*, IPR2023-00565, Pap.13 at 12. Moreover, the Delaware Litigation is a Hatch-Waxman (ANDA) case and, as such, is time-pressured to be completed before the expiration of the stay of regulatory approval under 21 U.S.C. §355(c)(3)(C) (there, June 5, 2025).

And again, if this IPR is instituted, it will be joined to the Mylan petition, so **there will be no one-year statutory deadline for the final written decision**: under §42.100(c) and §316(a)(11), the Board “may adjust th[is one-year] time period[]” and ignore the prior October 4, 2024 date without making any showing or meeting any other requirements. *E.g., Mylan Pharms. Inc. v. St. Regis Mohawk Tribe*,

IPR2016-01127, Pap.144, 5 n.4 (2018) (“[W]e are not under any statutory deadlines given the joinder of these proceedings under 35 U.S.C. § 315(c) (*see* § 42.100(c))....”); *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paps. 14, 30, 86 (following joinder of a single party raising the same grounds and prior art and diverging only in an expert’s declaration, final written decision issued 19 months and 17 days after institution of the original petition and 15 months and 29 days after joinder). Indeed, the Board regularly issues its final written decisions for joined proceedings more than a year after instituting the first of the joined petitions. *E.g.*, *Amerigen Pharms.*, Paps. 14, 30, 86; *see also, e.g.*, *Apple Inc. v. Traxcell Techs., LLC*, IPR2021-01552, Pap.18, 2 (May 25, 2022) (granting 3-and-a-half-month extension under §42.100(c) to one-year deadline to issue a final determination following institution and joinder of copycat petition, resulting in final written decision being due approximately a year after institution of copycat petition).

In support of its Motion for Joinder, Petitioner cites *LG Elecs., Inc. v. Memory Integrity, LLC* to argue that “joinder should have no impact on the schedule of the Mylan IPR.” Mot. for Joinder at 6 (citing IPR2015-01353, Pap.11, 6 (Oct. 15, 2015)). But Petitioner neglects to mention, including in its *Fintiv* arguments, that the *Memory Integrity* joinder resulted in a final written decision issuing more than 13 months after its institution date, exceeding the 1-year

statutory deadline. *Compare Apple Inc. v. Memory Integrity, LLC*, IPR2015-00163, Pap.18 (May 8, 2015) (Institution Decision), *with id.*, Pap.52 (June 21, 2016) (Final Decision). This only further supports PO’s point that institution and joinder of this Petition could lead to delays in PO receiving a final written decision in the Mylan IPR.

Because, if this Petition is instituted and joinder is granted, there are no constraints on the timing of the final written decision—and because, even if the Mylan IPR due date were considered, a final written decision would be due *after* the scheduled start of trial—this factor favors discretionary denial.⁴

⁴ While Petitioner may argue that the September 2024 trial date could be delayed, any such argument is speculative to begin with, and should in any event be disregarded because instituting and joining this Petition would mean *there is no deadline for the final written decision*. As to a possible trial delay, the Delaware district court stated at the end of a claim construction hearing in a different, separately filed lawsuit that it might “move that [Delaware Litigation] trial date a little bit” due to scheduling conflicts in September and October generally. EX2007, 3-4 (104:16-105:18). But the Court has yet to do so, or even to raise the issue in the Delaware Litigation. The Court also did not indicate whether trial would be rescheduled earlier or later (if at all). Indeed, as the Delaware Litigation

C. The Court and Parties Have Already Invested Significantly in the Parallel Litigation (Factor 3)

The Delaware Litigation has been pending since March 2022 and is now in its late stages. Much substantive work has already been done by both the parties and the Court:

Claim construction has issued. The parties have negotiated agreement on three '462 claim terms, and the Court heard oral argument and subsequently issued its claim construction order on the disputed term *six months ago*. EX2008, 2-3; *see Fintiv*, Pap.11, 9-10 (“district court claim construction orders may indicate that the court and parties have invested sufficient time in the parallel proceeding to favor denial”).

is a time-pressured Hatch-Waxman (ANDA) case, postponing trial in any significant way would be unlikely. *In re Brimonidine Pat. Litig.*, 2008 WL 4809037, at *2. There is thus no basis to treat the trial date as anything but September 2024. Even if the trial were later, the other factors still weigh in favor of discretionary denial. *Fintiv*, Pap.11, 9 (“If the court's trial date is at or around the same time as the projected statutory deadline or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors discussed herein.”).

Fact discovery is complete. Fact discovery in the district court litigation has been closed since December 15, 2023 (with the exception of a single discrete dispute regarding additional discovery relating to marketing and sales). EX2009, 2. During the fact discovery period, PO produced over 4.8 million pages of documents and the defendants collectively produced approximately 500,000 pages (with Petitioner alone producing approximately 158,000 pages, Mylan alone producing over 55,000 pages, and Sun alone producing approximately 240,000 pages). EX2019, 1 (PO's last production letter with an ending Bates number of NN-OZEM-004804104); EX2020 (compilation of the defendants' last production letters and last ending Bates numbers), 1 (Ppetitioner), 2 (Mylan), 3-4 (Sun). The defendants also collectively deposed six of PO's witnesses, including the '462 inventor (who submitted a declaration in the Mylan IPR in support of PO's swear behind argument (*see* EX2014, 2 (Declaration of Christine B. Jensen, Ph.D.)) and PO's marketing and sales witness (areas which, *e.g.*, relate to objective indicia of non-obviousness), Vanessa Costain. EX2021 (compilation of deposition notices), 1-5 ('462 inventor), 6-10 (marketing and sales witness); EX2010, 2.

Final invalidity contentions have been served. Petitioner served three rounds of invalidity contentions, including its initial invalidity contentions on October 20, 2022, and its final invalidity contentions (together with Mylan and all other defendants in the Delaware Litigation) on January 12, 2024. EX2022;

EX2001, 35; EX2023; EX2009, 3 (final invalidity contentions deadline); EX2018, 1 (supplemental invalidity contentions); *infra* n.8. Similarly, PO has previously responded to Petitioner's initial invalidity contentions and will be responding to its final invalidity contentions on February 9, 2024, two weeks from the date of this filing, and well before any institution decision is due. EX2015, 6; EX2009, 3 (deadline for response to final invalidity contentions).

Expert discovery is underway. By the April 26, 2024 expected institution decision date for this Petition, the parties will have advanced even further through expert discovery. Opening expert reports will be served on March 1, 2024, rebuttal expert reports served on April 5, 2024, and reply expert reports served on May 3, 2024, just days after the institution decision would be due in this proceeding. EX2009, 3-4. From there, it will only be a matter of five months before trial begins in the Delaware Litigation. EX2009, 3; EX2006, 38.

By the time the institution decision in this case would be due, all that would be left to complete in the Delaware Litigation is expert reply reports and depositions, the pre-trial order and motions, then trial. EX2009, 3-4.⁵ Thus, *Fintiv*

⁵ The case schedule does not contemplate any summary judgment motion filings, and this is, accordingly, not a litigation task yet to be completed. EX2006, 31

factor 3 weighs heavily in favor of discretionary denial. *Duplo U.S.A. Corp. v. MGI Digital Tech. S.A.*, IPR2023-00936, Pap.8, at 18 (Dec. 5, 2023) (“We agree with Patent Owner that there has been substantial investment by the parties and the district court in the parallel proceeding, including the completion of preliminary disclosures and claim construction, and ***the near-completion of discovery***. Under the circumstances, we find that the third *Fintiv* factor ***weighs heavily in favor of discretionary denial*** of institution.” (emphasis added)); *Samsung Elecs. Co. v. Mojo Mobility Inc.*, IPR2023-01091, Pap.11, 13-14 (Jan. 8, 2024) (“*Mojo Mobility*”) (finding *Fintiv* factor 3 “favors exercising our discretion to deny institution” given that “[f]act discovery is well underway (...fact discovery is set to close a little more than two months after the issuance of this decision) and substantial preparation for a [] *Markman* Hearing (including briefing) will be completed [in the same month as the institution decision]”); *Google v. Uniloc*, IPR2020-00115, Pap.8, 7 (finding factor 3 favored discretionary denial where “expert discovery will close in approximately six weeks [from institution], and a jury trial will begin in less than five months”).

(“Case Dispositive Motions. The Court will not entertain summary judgment motions.”).

In addition, Petitioner failed to file its IPR “at or about the time” it served its initial invalidity contentions in October 2022. *See* EX2022; EX2001, 35; *Mylan v. Janssen*, IPR2020-00440, Pap.17, 18-19; *Fintiv*, IPR2020-00019, Pap.15, 11-12 (May 15, 2020). Instead, Petitioner waited another *year*, until October 20, 2023, to file this IPR. Pet.67. Petitioner’s substantial delay in filing this IPR further weighs in favor of discretionary denial. *Mylan v. Janssen*, IPR2020-00440, Pap.17, 18-19; *Samsung v. Ancora*, IPR2020-01184, Pap.11, 18.

D. There Is Overlap Between Issues Raised in the Petition and in the Parallel Litigation (Factor 4)

There is significant overlap between the issues raised in this Petition and in the parallel proceedings, despite Petitioner’s *Sand Revolution* stipulation, and this factor weighs in favor of exercising discretion to deny institution. *Samsung Elecs. Co. v. Clear Imaging Rsch., LLC*, IPR2020-01402, Pap.12, 24-25 (Mar. 4, 2021) (“*Clear Imaging*”) (finding *Fintiv* “factor 4 weighs slightly in favor of exercising our discretion to deny institution under § 314(a),” “notwithstanding the [*Sand Revolution*] stipulation,” because “overlapping claims are challenged based on the same prior art” and noting that relying on the same prior art disclosures “would be analyzing and interpreting the same pieces of prior art, duplicating effort and potentially reaching inconsistent results”); *KeyMe, LLC v. The Hillman Grp. Inc.*, IPR2020-01028, Pap.12, 13-15 (Jan. 13, 2021) (“*KeyMe*”) (finding a *Sand Revolution*-style stipulation “favors the exercise of discretionary denial” given the

“concerns of inefficiency and the possibility of conflicting decisions’ when substantially identical prior art is submitted in both the district court and the *inter partes* review proceedings,” and distinguishing from *Sand Revolution* in that “the *Sand Revolution* petitioner’s district court invalidity contentions contained various prior art references not at issue in the IPR, including several prior art systems” and in contrast here, “Petitioner’s invalidity defenses in the district court were initially available in the IPR”); *see also Apple Inc. v. Maxell, Ltd.*, IPR2020-00408, Pap.13, 10-15 (Aug. 11, 2020) (finding differing grounds asserted in district court and in petition “substantially similar” and therefore “favor[ing] the exercise of discretionary denial”).

The Grounds here are: (1) anticipation in view of WO421; (2) anticipation in view of Lovshin; (3) obviousness based on WO421 in view of ’424; (4) obviousness based on WO537 in view of Lovshin; and (5) obviousness based on some combination of NCT657, NCT773, and ’424. Pet.4. In the parallel litigation, defendants are asserting invalidity based on, *inter alia*, four of the five references asserted here (WO421, Lovshin (referred to as “Lovshin 2009”), ’424⁶, and NCT657), as well as several references (WO’471, Madsbad 2011, and WO’530)

⁶ ’424 is the published application for the issued ’833 patent, and has the same substantive disclosures. *Compare* EX1016, *with* EX2011.

that are not asserted in this proceeding. EX2001, 2-32; EX2018, 6. This weighs against institution because the four overlapping references could continue to be asserted in litigation, and the Board and the district court “would be analyzing and interpreting the same pieces of prior art, duplicating effort and potentially reaching inconsistent results.” *Clear Imaging*, Pap.12, 24-25. Further, the additional references in the litigation are printed publications (to the extent they are prior art) and could have been asserted in an IPR. *KeyMe*, Pap.12, 13-15 (concluding *Sand Revolution* stipulation “does not eliminate clear overlap in the issues” and recognizing “all of Petitioner’s invalidity defenses in the district court were initially available in the IPR”); *Fintiv*, IPR2020-00019, Pap.15, 14 (considering overlap outside the context of a *Sand Revolution* stipulation and stating “Petitioner’s assertion of additional invalidity contentions in the District Court is not relevant to the question of the degree of overlap for this factor.”). Further, in both the IPR to which Petitioner seeks joinder and the Delaware Litigation, PO is swearing behind at least WO421 and presenting substantive arguments regarding objective indicia of non-obviousness. EX2015, 3-5; EX2014, 3, 4-15. This, too,

weighs against institution. *See Clear Imaging*, Pap.12, 24-25; *KeyMe*, Pap.12, 13-15; *Apple v. Maxell*, IPR2020-00408, Pap.13, 10-15.⁷

Ground 1 (anticipation by WO421) and Ground 2 (anticipation by Lovshin) are substantially similar to Petitioner's litigation grounds relying on WO421 and Lovshin and many of the same disclosures. *Compare* Pet.27-29, 36-37 *with* EX2018, 6-38.⁸ Additionally, both Ground 3 (WO421 in view of U.S. Patent Pub. No. 2007/0010424) and Ground 4 (WO537 in view of Lovshin) overlap with the

⁷ To the extent Petitioner argues these issues should be ignored because the Petition to which this IPR would be joined involves these issues regardless of whether Petitioner is joined, Petitioner's arguments are misplaced. First, as explained above, the Petition, including discretionary denial issues, are considered *before* the Board determines whether to join the case. *See LG v. Ancora*, IPR2021-00581, Pap.16, 6; *Facebook*, 973 F.3d at 1332. Second, to the extent Mylan settles with PO before the Mylan final written decision issues, the case would likely be *terminated* to the extent other parties are not joined, thus avoiding the potential for conflicting decisions.

⁸ PO relies on Petitioner's Supplemental Invalidity Contentions here (dated November 2, 2023) as PO's counsel here has not been able to get access to Petitioner's January 12, 2024 Final Invalidity Contentions.

precise obviousness grounds asserted in litigation. *Compare* Pet.4, with EX2018, 6-38. Further, Petitioner’s *Sand Revolution* stipulation here will not actually narrow the issues in the litigation because the parallel litigation involves multiple other defendants that are not subject to the stipulation. *See Samsung v. Ancora*, IPR2020-01184, Pap.11, 21-22 (recognizing co-defendants are not bound by petitioner’s *Sand Revolution* stipulation in analyzing factor 4, and concluding factor four weighed in favor of non-institution because “overlapping claims are challenged based on the same prior art”). The stipulation, therefore, should carry no weight because, *e.g.*, Zydus and Rio will still be able to assert those same grounds in the parallel litigation to which Petitioner (and Mylan) remain parties. And Ground 5 relies on many of the same disclosures of NCT657 that Petitioner relies on in litigation. *Compare* Pet.22, 54-55 with EX2018, 7. Petitioner has also asserted prior art (*e.g.* Madsbad) and combinations in the litigation that aren’t asserted in the IPR. *See* EX2018, 6, 15, 19, 22, 25, 28, 30, 36.

Moreover, Petitioner’s choice of a *Sand Revolution* stipulation—rather than a broader *Sotera* stipulation—is particularly telling in its role as a would-be copy-cat joiner. Petitioner is likely to attempt to take advantage of the Federal Circuit’s decision in *Network-1 Technologies, Inc. v. Hewlett-Packard Co.*, 981 F.3d 1015, 1027 (Fed. Cir. 2020) that limited the scope of what Petitioner “could have raised” (under §315(e)(2)) to the grounds actually raised in the original IPR. Thus,

Petitioner's approach would preserve Petitioner's ability (*unlike* Mylan) to escape the broader estoppel that would have applied if Petitioner had filed its own original petition and not delayed 18 months before copying and seeking to join Mylan's petition.

'462 has 10 claims, including only one independent claim, which is challenged here. Petitioner does not assert that "[t]he claim that is the focus of the parties' arguments in this proceeding, independent claim 1" is not "common to both proceedings...." *Mojo Mobility*, Pap.11, 16. Additionally, Petitioner here does not address whether there are any non-overlapping claims or assert that any such "non-overlapping claims differ significantly... or that it would be harmed if institution of non-overlapping claims is denied." *Samsung v. Ancora*, IPR2020-01184, Pap.11, 21 (citing *Fintiv*, Pap.11, 13 & 13 n.25; *Next Caller*, Pap.10, 14).⁹ Therefore, even to the extent there is incomplete overlap of the claims, these facts

⁹ PO stipulates that if the Board denies institution here based on *Fintiv*, and to the extent any claims challenged here are not asserted in the Delaware Litigation, it will not seek to assert those claims in the Delaware Litigation against this Petitioner. *TCO AS v. NCS Multistage Inc.*, PGR2020-00077, Pap.16, 16-17 (Feb. 18, 2021).

do not weigh against non-institution, and this factor still weighs in favor of discretionary denial. *Samsung v. Ancora*, IPR2020-01184, Pap.11, 21.

E. Petitioner Is a Defendant in the Parallel Litigation (Factor 5)

As noted above, Petitioner and Patent Owner are parties to the parallel Delaware Litigation, where Petitioner is a defendant, along with Mylan. Therefore, this factor weighs in favor of exercising discretion to deny institution. *Fintiv*, Pap.11, 13-14.

F. Other Circumstances that Impact the Board’s Exercise of Discretion, Including the Merits (Factor 6)

For Petitioner to overcome the weight of the other *Fintiv* factors and avoid discretionary denial, it has the burden to show “compelling merits,” which is a higher standard than the reasonable likelihood standard required for institution. *Commscope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Pap.23, 3 (Feb. 27, 2023) (precedential) (quoting *USPTO Interim Procedure for Discretionary Denials* at 4). Petitioner asserts that their Grounds are “compelling” simply because it presents new grounds and evidence not presented in prosecution. Pet.64-65. But this assertion says nothing about the strengths of the grounds.¹⁰ In addition, the

¹⁰ Even if comparisons of evidence were to be made to prosecution, PO has presented rebuttal evidence in the Mylan IPR regarding swear-behind and

institution of Mylan’s IPR is irrelevant: “the mere fact that a party may have met its institution burden is not the same as an argument as to the particular strengths (or weaknesses) of the challenge[.]” *LG v. Ancora*, IPR2021-00581, Pap.16, 11. Further, even as to substance, Petitioner was aware of PO’s intent to swear behind prior art and rely on objective indicia of non-obviousness, yet chose not to address those issues. EX2015, 2-5.

V. Institution Should Additionally Be Denied Because This Petition Was Filed After the One-Year Bar Date

Section 315(b) bars the filing of IPRs “if the petition requesting the proceeding is filed more than 1 year after” the petitioner was “served with a complaint alleging infringement of the patent.” A petitioner that “*properly files a petition*” for IPR may be joined to an instituted IPR. §315(c). The Federal Circuit has interpreted these statutes to allow for copycat petitions seeking joinder (and not just the joinder motions themselves) to be filed more than a year after that petitioner was served with a complaint alleging infringement of the challenged patent. *Network-1*, 981 F.3d at 1020. However, whether such petitions are, in fact, “*properly file[d]*” is an issue currently being addressed in a petition for *certiorari* at the Supreme Court, which asserts that they are *not*. *VirnetX Inc. v. Mangrove*

objective indicia of non-obviousness, which were similarly not presented in prosecution. EX2014, 3, 4-15.

Partners Master Fund, Ltd., No.23-315, Dkt.1, at 11 (U.S. Sept 20, 2023). Similar to the petition at issue in *VirnetX*, the Complaint asserting infringement of '462 here was served on March 4, 2022, and the Petition was filed approximately nineteen and a half months later. EX2012; EX2013. Thus, for the purpose of preserving this issue so that this may be addressed by the Supreme Court, PO states that institution should be denied because Petitioner's copycat Petition was not "properly filed." §315(c). And in any case, Petitioner's delay in filing an IPR here provides a separate basis for discretionary denial under §314(a). *See Mylan Lab 'ys Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) ("The Director is permitted, but never compelled, to institute an IPR.").

VI. Conclusion

For all of the foregoing reasons, the Board should exercise its discretion to deny the Petition under §314 and, because the long-delayed Petition was filed after its one-year deadline and thus was not "properly filed," under §315(c).

Respectfully submitted,

Dated: January 26, 2024

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CERTIFICATE OF WORD COUNT

The undersigned certifies that the foregoing 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 5,594 words, excluding the parts of the brief exempted by 37 C.F.R. §42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of NOVO NORDISK'S PRELIMINARY RESPONSE UNDER 37 C.F.R. §42.107 and the accompanying exhibits have been served in their entirety on January 26, 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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