

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, INC.,
Petitioner

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner

IPR2025-00731
Patent No. 11,925,661

PATENT OWNER'S BRIEF IN SUPPORT OF DISCRETIONARY DENIAL

LIST OF EXHIBITS

Exhibit	Description
2001	U.S. Patent 10,632,150 (“Thomas”)
2002	Declaration of Gerald Sakowski
2003	C.A. 24-00846 (D. Del.), D.I. 61 Memorandum Opinion granting preliminary injunction motion dated 9/23/2024
2004	LexisNexis Patent Advisor Examiner Report for Al-Awadi, Danah J., retrieved April 14, 2025
2005	Comparison of Thomas (Ex. 2001) with WO2020/081118 (the “CMP-PCT”) (Ex. 1007)
2006	Declaration of Barrett Rabinow, Ph.D.
2007	Curriculum Vitae of Barrett Rabinow, Ph.D.
2008	Rangel-Frausto et al., “Should we use closed or open infusion containers for prevention of bloodstream infections?” <i>Annals of Clinical Microbiology and Antimicrobials</i> 2010, 9:6 (“Rangel-Frausto 2010”))
2009	Rosenthal et al., “Prospective study of the impact of open and closed infusion systems on rates of central venous catheter–associated bacteremia,” <i>American Journal of Infection Control</i> , May 2004, Vol. 32, No. 3, pp. 135-141 (“Rosenthal 2004”)
2010	Franzetti et al., “Impact on rates and time to first central vascular-associated bloodstream infection when switching from open to closed intravenous infusion containers in a hospital setting,” <i>Epidemiol. Infect.</i> (2009), 137, 1041–1048 (“Franzetti 2009”)
2011	Graves et al., Open versus closed IV infusion systems: a state based model to predict risk of catheter associated blood stream infections,” <i>BMJ Open</i> 2011; 2:e000188. doi:10.1136/bmjopen-2011-000188 (“Graves 2011”)

Exhibit	Description
2012	Lutwick et al., “Managing and preventing vascular catheter infections: A position paper of the international society for infectious diseases,” <i>International Journal of Infectious Diseases</i> , 2019, 84:22-29 (“Lutwick 2019”)
2013	U.S. Patent 11,141,430 (“Koneru”)
2014	The Joint Commission. <i>Preventing Central Line–Associated Bloodstream Infections: Useful Tools, An International Perspective</i> . Nov 20, 2013. (“Joint Commission 2013”)
2015	Docket sheet as of June 27, 2025, in <i>Nivagen v. Amneal</i> , C.A. 24-00846 (D. Del.)
2016	Public version of Opening Brief in support of Preliminary Injunction, <i>Nivagen v. Amneal</i> , C.A. 24-00846 (D. Del.) D.I. 22
2017	Public version of Answering Brief on Preliminary Injunction in <i>Nivagen v. Amneal</i>
2018	Public version of Reply in support of Preliminary Injunction in <i>Nivagen v. Amneal</i>
2019	(Reserved)
2020	D.I. 93, Public version of Answer and Counterclaims (D.I. 91) in <i>Nivagen v. Amneal</i>
2021	D.I. 95 Brief in Support of Motion to Dismiss in <i>Nivagen v. Amneal</i>
2022	D.I. 101 Public Version of Opposition Brief on Motion to Dismiss in <i>Nivagen v. Amneal</i>
2023	D.I. 102 Reply Brief on Motion to Dismiss in <i>Nivagen v. Amneal</i>
2024	Email from Yixin Tang to Defendants re: Sotera stipulation

Exhibit	Description
2025	(Reserved)
2026	Declaration of Mansoor M. Amiji, Ph.D. in <i>Nivagen v. Amneal</i> Preliminary Injunction briefing, D.I. 29

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I. INTRODUCTION

Petitioner challenges the claims of the '661 patent based on three grounds, all of which merit discretionary denial. Ground I is a dressed-up written description argument, contending that the challenged claims are unsupported by the disclosures in Nivagen's priority application ("Nivagen-1," or "Pandya" in the parallel litigation, Ex. 1006) such that the priority application is anticipatory prior art. The priority application issued as U.S. Patent No. 11,813,291 (the "'291 patent"), which is the subject of related IPR2021-00779. Nivagen-1, however, was squarely before the Office during the '661 patent application examination. Moreover, the same arguments presented here concerning anticipation by Nivagen-1 have been tried before, but rejected by the District Court in Petitioner's failed invalidity challenge there, when Petitioner tried and failed to establish a substantial question of invalidity as to the '661 patent in an unsuccessful bid to avoid a preliminary injunction.

Petitioner's other two Grounds—which are nearly identical to the Grounds raised in its related IPR2025-00779—depend principally upon a determination that Petitioner's so-called CMP Art renders the challenged claims invalid. The CMP Art consists of two related references originating from CMP Development LLC ("CMP"). The predominant reference is International Patent Application Publication No. WO2020/081118 (the "CMP-PCT") (Ex. 1007) purporting to disclose a concentrate product comprised of potassium phosphates. The secondary

reference is the FDA drug label related to the same composition (the “CMP-FDA”) (Ex. 1008).

The CMP Art, however, was already before the Patent Office and was considered by the Examiner during prosecution, who found that it did not pose patentability issues. Specifically, as discussed below in Part II.A, the Examiner acknowledged in the Notice of Allowance that he considered the U.S. counterpart to CMP-PCT, namely U.S. Patent No. 10,632,150 by Thomas, et al. (“Thomas,” Ex. 2001). The CMP CEO provided a declaration in support of Patent Owner’s Request for Discretionary Denial, to confirm that Thomas is identical in all material ways with CMP-PCT. (Ex. 2002). Petitioner’s other prior art references are not only cumulative of what was before the Patent Office during examination, but also inapposite as they are related to products that are the opposite of the claimed invention. As Petitioner does not allege any error on the part of the Examiner in allowing the patent to issue over Thomas, institution is inappropriate under 35 U.S.C. § 325(d).

Moreover, the Petition advances invalidity arguments already brought in a parallel ongoing District Court litigation—a point Petitioner fails to mention—making institution inappropriate under 35 U.S.C. § 325(a). The District Court rejected Petitioner’s invalidity theories, ruling in favor of Patent Owner. (Ex. 2003 (Preliminary Injunction Opinion)).

Further still, the factors outlined in the Memorandum on Interim Processes for PTAB Workload Management underscore that discretionary denial is appropriate here. Institution should be denied.

II. INSTITUTION SHOULD BE DENIED UNDER 35 U.S.C. § 325(d)

Section 325(d) provides that the Director may deny institution when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). *Advanced Bionics* provides a two-part framework for evaluating whether denial under Section 325(d) is warranted: (1) whether the same or substantially the same prior art or argument previously was presented to the Office; and (2) if the first part is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Paper 6 at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential).

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) further identifies the following non-exclusive factors in analyzing the *Advanced Bionics* framework: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the

extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art; (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *Id.* at 17–18 *see also NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 11-12 (P.T.A.B. Sep. 12, 2018) (precedential) (quoting *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17- 8 (P.T.A.B. Dec. 15, 2017) (informative)).

The prosecution history of the '661 patent, like that of its parent '291 patent, is short but informative. The Examiner carefully considered references that are relevant here. That is, the Notice of Allowance attaches, *inter alia*, the prior art cited and relied upon in examination. (Ex. 1002, p. 66). This prior art includes just three patents, one of which is Thomas. *Id.* As explained below in Section II.A., the Examiner's evaluation of Thomas—which, as noted, is identical to the CMP-PCT that Petitioner relies upon here—renders the Petition a duplicative of what was already before the Office. Additionally, the other patents considered by the Examiner are, as explained below in Section II.B., cumulative of Petitioner's secondary references. Even in view of this art, the Examiner readily allowed the

claims to issue in substantially the same form as originally filed.¹ For the reasons below, the Director should exercise her discretion to deny the institution of this challenge under the *Advanced Bionics* and *Becton Dickinson* framework.

A. During Prosecution, the Office Already Considered Petitioner’s Ground I Art

In Ground I, Petitioner argues that the priority application with the serial number 17/499,001 (“Nivagen-1,” which Petitioner referred to as “Pandya” during the preliminary injunction proceeding in the District Court, Ex. 1006)—which matured into the ’291 patent—does not provide sufficient written description support for the invention claimed in the ’661 patent. Petition at 5-12. Petitioner asserts that, because the disclosures in the ’661 patent concerning phosphorous concentrations as low as 1.5 mmol/100 ml were newly added in a continuation-in-part application to Nivagen-1, the priority date of the ’661 patent is its filing date of September 5, 2023 rather than the priority date derived from the filing of Nivagen-1 and its priority document, a provisional application. *See* Petition at 12-13.

During prosecution of the ’661 patent, however, the applicant plainly stated in its as-filed specification that “[t]his application is a continuation-in-part of application of our co-pending US non-provisional application with the serial

¹ The examiner, Mr. Awadi, is in line, statistically, with other Examiners in the relevant Art Unit concerning allowance rates or reversals. (*See* Ex.2004)

number 17/499,001” (Ex. 1002 at p. 114, [0001]), which is the application that matured into the ’291 patent. The examiner nevertheless found written description support and did not find any patentability issues over the prior art, including the co-pending application. (*See generally*, Ex. 1002 (accepting Patent Owner’s terminal disclaimer and finding no issues with respect to written description)).

In any event, Petitioner’s premise of Ground I—that there is not sufficient disclosure in the priority application to support the challenged claims—is wrong and flatly contrary to established Federal Circuit law. The ’291 patent (which includes the ’001 Application disclosures) recites “more preferred embodiments” with phosphorus concentration at “not more than 2.7 mmol/100 ml” or “not more than 5.5 mmol/100 ml.” *See* Petition at 8-9 (discussing Ex. 1006 at [0044]-[0045]). Petitioner and its expert attempt to disregard or misinterpret these disclosures, which plainly refer to “lower concentrations” in the claimed range, including the “as low as 1.5 mmol/100 mL” concentrations. That the number “1.5” may not appear in the priority ’291 patent specification does not mean that there is insufficient support for the ranges recited in the ’661 patent challenged claims. *See Rai Strategic Holdings, Inc. v. Philip Morris Products S.A.*, 92 F.4th 1085, 1090 (Fed. Cir. 2024) (“The specification need not expressly recite the claimed range to provide written description support.”); *Indivior UK Limited v. Dr. Reddy’s Laboratories S.A.*, 18 F. 4th 1323, 1352 (Fed. Cir. 2021) (patent application related

to sublingual or buccal film compositions for treating opioid dependence had written description support for claim reciting “about 48.2 wt %” as amount of polymer, even though the number “48.2 wt %” was not explicitly set forth in application); *see also In re: Selenious Acid Litigation*, Case No. 2:24-cv-07791, 2025 WL 1900949 (D.N.J. July 8, 2025) at *9-12 (finding patent claims to be supported by written description when both ends of a claimed range in a limitation are listed in the specification, and the language of the specification does not point to a different invention and citing abundant Federal Circuit and District Court cases).

Accordingly, the Board should reject Petitioner’s baseless arguments in Ground I and deny institution.

B. During Prosecution, the Office Already Considered Petitioner’s Primary CMP Art

Petitioner’s CMP Art is the same as Thomas, considered and found unavailing by the Examiner during prosecution. Exhibit 2005, which is a redline comparison of CMP-PCT and Thomas, readily demonstrates that Thomas and CMP-PCT are identical other than formatting formalities. Furthermore, Mr. Gerald Sakowski, who served as the CEO of CMP Development LLC from July 2013 to April 2025, submitted a declaration testifying about the relationship of CMP-PCT and Thomas and stating that “there are no substantial differences between the two references. The only differences are non-substantive.” Ex. 2002 at ¶¶7-10. Mr. Sakowski also

states that “no reasonable person could conclude that substantial differences exist between the two references.” *Id.* at ¶11.

By Petitioner’s own admission, the CMP-FDA drug label adds nothing that is not already disclosed in the CMP-PCT. *See generally*, Petition (lumping CMP-PCT and CMP-FDA together as if it is one piece of CMP Art). Petitioner acknowledges that CMP-PCT and CMP-FDA include the same information concerning the phosphate solutions at issue. Petition at p. 41 n.14, p. 49. Accordingly, Petitioner’s contention that the CMP Art poses patentability issues was already rejected by the Office when the Examiner effectively evaluated the CMP Art through consideration of Thomas. Petitioner’s attempt to avoid denial under 35 U.S.C. § 325(d) by recycling the same reference from the prosecution history but under a different title and without any explanation of the differences should not be countenanced.

C. Petitioner’s Three Remaining Secondary References in Grounds II and III Add Nothing New to What Was Already Before the Office

Petitioner’s recycling of Thomas under a different name is just the beginning of Petitioner’s duplicity. During prosecution, the Examiner considered two other patents: U.S. Patent No. 11,141,430 to Koneru et al (“Koneru”) and U.S. Patent No. 10,342,813 to Pizza (“Pizza”). (Ex. 1002, p. 66). After considering this art, the Examiner allowed the claims to issue, stating that Koneru is the closest prior art and that even Koneru did not provide motivation to arrive at the invention as claimed. (*Id.*, pp. 26, 39). Petitioner’s remaining Ground II references (Terlevich with an

optional reliance on Ogawa) as well as its sole additional Ground III reference (Nevakar)—all of which are sparingly relied upon relative to the CMP Art—are cumulative to Koneru and Thomas and similarly add nothing new to what was before the Office during prosecution.

For example, because CMP-PCT does not disclose “an isotonic sterile ready-to-use” solution as required by the ’661 patent claims, Petitioner relies on Terlevich as purportedly disclosing a “sealed semi-rigid cylindrical polyethylene container with a twist-off seal at one end and a ring tab at the other.” Petition at 36-37. However, Terlevich does not disclose a *sterile* or *ready-to-use* product and thus does not add to the disclosure of the CMP Art or Thomas, which also disclose a product that is neither sterile nor ready to use. (See Ex. 2006, Declaration of Barrett Rabinow, Ph.D., at ¶¶18-22, 31-45). As Dr. Rabinow explains, Terlevich discloses a “Phosphates Polyfusor” or “PPF” product used at one point by the United Kingdom’s Public Health Service, which, due to its use of “semi-rigid” and *not flexible* containers, required opening a vent on a semi-rigid container to let in ambient air before the solution in the container can flow out properly. (*Id.* at ¶¶21-27).

As Dr. Rabinow explains, a POSA would know that the necessary step of “opening a vent to let the hospital air in” can potentially have a detrimental effect in both sterility and the ability to readily use the solution. (*Id.* at ¶¶18-30). This

necessary step before the PPF solution can be properly infused into a patient introduces a detrimental component (hospital air) which can contaminate the potassium phosphate solution prior to administration to the patient. (*Id.* at ¶¶31-44). This contamination problem in an “open system” like the PPF product was well known by the time of the invention claimed in the challenged ’661 patent. (*Id.*). The PPF product described in Terlevich was known to be an *open and non-sterile* system, which is directly opposite of the closed, sterile, RTU product recited in the ’661 patent. (*Id.* at ¶¶18-44.). Therefore, Terlevich does not add to the disclosure of CMP Art or Thomas, which also requires an admixture step that potentially introduces contamination before infusion and thus does not disclose a product that is sterile or ready to use.

Petitioner’s argument that Terlevich purportedly teaches the claimed “flexible polymeric container” is not only wrong, but also duplicative of the disclosures in Koneru that were rejected by the Examiner. Specifically, Petitioner relies on Terlevich to argue that putting potassium phosphates solution with a nutrient concentration suitable for infusion in a semi-rigid container (which is *not* a flexible container in reality, Ex. 2006 at ¶¶18-29) was known in the art. But Koneru, which was cited during prosecution, already disclosed placing injectable formulations for parenteral administration “in an infusion container,” which can be a rigid “glass vial” or a polymeric or plastic container which may or may not be rigid. (*See* Ex. 2013,

Koneru at 14:42-67) (disclosing that “formulations in the said containers are prepared by diluting any of the phosphate ion concentrations,” to make them suitable for infusion). Terlevich thus adds nothing substantial to the prior art the Examiner considered and analyzed and rejected.

Petitioner optionally relies on Ogawa as disclosing low aluminum, but this also adds nothing to Koneru, which discloses “compositions comprising phosphate salts having low levels of aluminum, as well as other elemental impurities.” (Ex. 2013 at Abstract).

Finally, Petitioner also cites Nevakar (Ex. 1011) in Ground III as additional art that purportedly discloses “flexible polymeric containers suited for use with ready-to-use solutions, which containers may include a secondary metallized overwrap.” Petition at 62-64. Nevakar is not specific to any potassium phosphates compositions. Petitioner’s stated purpose for Nevakar is to teach storage stable RTU bags and other packaging elements. As noted above, however, Koneru teaches these elements, which were considered and rejected during prosecution. (Ex. 2013, at 14:63-67 (“Such polymeric containers are known in the art and are widely used in the infusion practice. The equipment to manufacture the containers, and the equipment to fill such containers with the drug product are also known in the pharmaceutical arts.”)). As such, Nevakar also adds nothing more to the analysis of Koneru conducted by the Examiner.

D. Petitioner Has Not Identified a Material Error by the Office

In evaluating whether Petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims, the Board considers the following *BD* factors: the extent to which the asserted art was evaluated during examination, whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art, and the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments. *See Advanced Bionics*, Paper 6 at 9-10. Analysis of these factors confirms Petitioner has failed to identify any material error and to present any additional evidence or facts that warrant institution.

Although prosecution of the '661 patent was short, the Office made clear that it reviewed Thomas, Koneru, and other cited art. (Ex. 1002, at p. 66). That the claims of the '661 patent were precisely drawn to the invention and able to swiftly overcome the prior art supports the merits of the invention as claimed. Moreover, Petitioner has not identified any material error in the Office's examination and ultimate grant of the '661 patent, nor does Petitioner challenge any incorrect claim construction, making denial of institution appropriate. *Advanced Bionics*, Paper 6 at 8-9. It is Petitioner's burden to demonstrate that the previously presented art teaches the limitations of the challenged claims, and that no reasonable examiner could have found otherwise. *Ecto World, LLC, et al. v. Rai Strategic Holdings, Inc.*, IPR2024-

01280, Paper 13 at 9 (P.T.A.B. May 19, 2024) (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”). To the extent Petitioner attempts to do so in response to this brief, Nivagen reserves all rights to reply.

In sum, this is a case where the Examiner applied the asserted prior art or substantially the same prior art during examination. It would exalt form over substance to ignore the settled law that when the prior art asserted for invalidity was art already considered by the Examiner, the challenger’s burden of invalidity is significantly heightened. *See, e.g., BlephEx, LLC v. Myco Industries, Inc.*, 24 F.4th 1391, 1402 (Fed. Cir. 2022); *Shire LLC v. Amneal Pharmaceuticals, LLC*, 802 F.3d 1301, 1307 (Fed. Cir. 2015); *Cadence Pharmaceuticals Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1375 (Fed. Cir. 2015); *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008). Because the Petition only presents duplicative, cumulative art that was already before the Office during examination and Petitioner has not identified any error, institution should be denied.

III. INSTITUTION SHOULD BE DENIED UNDER 35 U.S.C. § 314(a)

The Petition implicates substantially similar invalidity arguments and prior art that have been preliminarily decided by the District Court. Additionally, as exemplified by the procedural history of the parallel and ongoing litigation, outlined below, there have been considerable investments by the parties and the court in these parallel proceedings, making institution inefficient and duplicative. Accordingly, as explained below, the Board should exercise its discretion and deny institution.

A. Procedural Posture of the Parallel District Court Litigation

On July 19, 2024, a full year ago, Patent Owner Nivagen filed suit against Petitioner Amneal in Delaware for declaratory judgment of future patent infringement based on Amneal's public disclosure that it expected FDA approval and commercial launch for its potassium phosphates RTU drug product. *Nivagen Pharmaceuticals, Inc. v. Amneal Pharmaceuticals Inc. et al.* Case No. 24-cv-00846 (D. Del, July 19, 2024), D.I. 1 (Ex. 2015 (case docket)). The patents at issue in the District Court are the '291 patent and the '661 patent. (*Id.*, Docket at D.I. 3). Petitioner challenges the patentability of the '661 patent in this IPR proceeding and that of the '291 patent in IPR2025-00779.

Soon thereafter, the FDA granted final approval of Amneal's drug application, thus allowing Amneal to launch its product. Patent Owner amended its complaint against Amneal to address this new development. (*Id.*, Docket, at D.I. 21). On

August 13, 2024, Nivagen promptly moved for a temporary restraining order and preliminary injunction, and Amneal opposed the motion. (*Id.*, Docket at D.I. 12-15; *see also* Ex. 2016, redacted version of the PI/TRO Motion Opening Brief). Nivagen relied on the declarations of Dr. Rabinow and its CEO Mr. Jay Shukla. (Ex. 2015, Docket at D.I. 14-15). Petitioner opposed the motion and relied on the same expert declarant Dr. Amiji as it does for the Petition. (*Id.*, Docket at D.I. 29; *see also* Ex. 2017, redacted version of Opposition Brief; Ex. 2026)). Nivagen then filed a reply brief (Ex. 2015, D.I. 32, *see also* Ex. 2018, redacted version), relying on additional expert declarations by Dr. Peter A. Malaspina and Dr. Dennis Jenke (Ex. 2015, D.I. 33 and 34).

The Court held an injunction motion hearing on September 5, 2024. (*Id.*, Minute Entry). Throughout September 2024, the parties engaged in numerous post-hearing filings related to (1) Petitioner's motion to strike expert opinion, (2) "best cases" supporting each side's position, and (3) the injunction bond amount. (*Id.*, Docket, D.I. 44-46, 49-59). The Court denied Petitioner's motion to strike. (*Id.*, Docket at D.I. 60). On September 23, 2024, the Court granted Patent Owner's motion for preliminary injunction and temporary restraining order, and issued a detailed opinion. (*Id.*, Docket at D.I. 61, 62). As discussed in more detail below, in its 29-page memorandum order, from pages 4 to 13, the Court evaluated and rejected

substantially the same anticipation- and obviousness-based invalidity arguments Amneal is again raising in the Petition. (Ex. 2003).

On September 24, 2024, the District Court issued an order setting the injunction bond at \$30 million. (Ex. 2015, Docket at D.I. 63). The parties sent additional letters to the Court regarding the bond amount. (*Id.*, Docket at D.I. 66, 68, 76-78). Unfortunately, Nivagen was unable to pay the bond amount and, on October 15, 2024, the District Court terminated the injunction order. (*Id.* Docket at D.I. 86). With the lack of entry of the injunction, Amneal thereafter launched its admittedly infringing (as to the '661 patent) product.

Following the Court's October 15, 2024 Order terminating the injunction order, Patent Owner amended the complaint to seek damages. (*Id.*, Docket at D.I. 88). On December 6, 2024, Petitioner answered the Second Amended Complaint and asserted counterclaims, including a Fifth Counterclaim of "inequitable conduct" and a Sixth Counterclaim of "wrongful injunction." (*Id.*, Docket at D.I. 91; *see also* Ex. 2020, Redacted Answer and Counterclaims, pp. 58, 66). Patent Owner then moved to dismiss the Fifth and Sixth Counterclaims for failure to state a claim, and to strike Defendants' Second, Third, and Seventeenth Affirmative Defenses. (Ex. 2015, Docket at D.I. 94-95; Ex. 2021, opening brief in support of the Motion to Dismiss). Petitioner opposed the motion to dismiss on February 4, 2025. (Ex. 2015,

Docket at D.I. 100; *see also* Ex. 2022, redacted version). Patent Owner filed its Reply Brief on February 21, 2025. (Ex. 2015, Docket at D.I. 102; Ex. 2023).

During the briefing of the motion to dismiss, Patent Owner Nivagen also answered those of Amneal’s counterclaims that are not subject to the motion to dismiss. (Ex. 2015, Docket at D.I. 98). The motion to dismiss was fully briefed by February 21, 2025, but the Court has not ruled on it, or set a schedule for the case. Less than two months later, on April 11, 2025, Amneal filed this Petition.

On May 12, 2025, litigation counsel for Patent Owner wrote to litigation counsel for Petitioner, and asked if Amneal intended to file a *Sotera* stipulation in the parallel litigation. (Ex. 2024). Amneal’s counsel has not responded to that inquiry. In view of the foregoing posture of the parallel proceeding, Petitioner’s casual statement that “[t]he Litigation is in its infancy” is disingenuous. Petition at 13. Nowhere in the Petition does Petitioner disclose that the District Court case was filed a year ago, the Court read full briefing papers regarding the merits of Petitioner’s patent anticipation and obviousness defenses, conducted an hours-long injunction motion hearing, and then issued detailed preliminary injunction order and memorandum opinion on the merits that categorically rejected Petitioner’s invalidity challenges.

B. Analysis of *Fintiv* Factors

1. Factor 1: The Nivagen Litigation Has Not Been Stayed

Petitioner has not filed any motion to stay the district court case pending resolution of the IPR nor has it indicated any intent to do so. In the event Amneal determines to file a motion to stay, Nivagen will oppose the motion. This factor weighs in favor of denying institution or is neutral. *See Google LLC v. Uniloc LLC*, IPR2020-00115, Paper No. 8 at 7 (P.T.A.B. 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”).

2. Factor 2: Proximity of the Trial Date

There is no trial date yet scheduled because of the pending motion to dismiss. It is expected, however, that the case schedule will be rapid and the time to trial will be short. This is because both the infringement and invalidity issues in the case are streamlined. During the preliminary injunction proceedings, Nivagen only asserted infringement of the '291 patent on a Doctrine of Equivalents theory on one claim element. (Ex. 2016, at 5-8). On the other hand, Amneal did not contest infringement of the '661 patent during the preliminary injunction proceedings. (Ex. 2017, at 9-12). On the patent validity or invalidity issues, as discussed with respect to Factor 4, below, Amneal relies on the same expert Dr. Amiji and substantially the same prior art references to make the same arguments both in District Court and here.

The trial court has already extensively considered the invalidity arguments during the preliminary injunction proceeding. Furthermore, the parties are in a head-

to-head competition in the nascent potassium phosphates RTU product market. The parties should be incentivized to reach trial quickly to resolve the dispute on the merits and obtain certainty in the parallel litigation, upon the Board's denial of the Petition.

Amneal's generalized statistical data about Judge Williams's timelines is not reliable because it is not specific to this situation where the parties and issues are few and the issue of invalidity has already been preliminarily addressed. The parties are also the only two competitors in a nascent market. Additionally, Amneal's statistics include cases where a stay has been granted, which would likely cause a longer time to trial date. This factor favors Nivagen or at best is neutral, and supports denial of institution.

3. Factor 3: Investment in Parallel Proceeding by the Court

Nivagen filed its initial complaint in the District Court a year ago. Shortly thereafter, and as noted above, the parties briefed substantially the same invalidity issues before the District Court in the preliminary injunction context and the Court ruled in favor of Nivagen, holding that Amneal did not even raise a substantial question of patent invalidity. (Ex. 2003). In doing so, the trial court conducted intensive injunction analysis, analyzed extensive briefing (filed both before and after the PI/TRO motion hearing), and conducted an hours-long motion hearing, after which it issued a 29-page order, of which a dozen pages carefully analyzed and

rejected the invalidity arguments Amneal seeks to raise again here. Amneal had a full and fair opportunity to be heard.

As shown in the procedural posture of the parallel litigation set forth above, this factor strongly favors Nivagen and supports discretionary denial.

4. Factor 4: Overlap of Issues in the Petition and Parallel Proceeding

Petitioner relies exclusively on Nivagen-1 (Ex. 1006) for Ground I and primarily on the CMP Art (Exhibits 1007 and 1008/1027) for Grounds II and III. Not only were these references previously before the Office as explained above in Sections II.A and II.B, Petitioner arguments concerning these prior art overlap with its invalidity challenge raised in the parallel District Court proceeding. Specifically, during the preliminary injunction proceeding at the District Court, Petitioner challenged the validity of the '661 patent on two grounds, the first of which is identical to Ground I and the second of which is substantially similar to Grounds II and III.

Turning first to the overlap with regard to Ground I, both here and in the District Court, Petitioner relied exclusively on Nivagen-1 (referred to as “Pandya” in the parallel litigation) as anticipatory art, after first arguing that the claims of the '661 patent are not entitled to a priority date before September 5, 2023 because the '661 Patent's disclosure of the lower phosphorous concentrations first appeared in the application for the '661 Patent filed on September 5, 2023. (*Compare* Petition

at 5-13 *with* Ex. 2017 (PI/TRO Motion Opposition Brief) at 9-10 (internal pagination)). Both here and in the District Court, Petitioner offered that Nivagen-1/Pandya anticipates the '661 patent claims by disclosing a formulation within the scope of those claims. (*Compare* Petition at Ground I *with* Ex. 2017 (Opposition Brief to the PI/TRO Motion) at 10).

The District Court rejected Petitioner's Nivagen-1/Pandya argument. (*See* Ex. 2003 (District Court Preliminary Injunction Opinion) at 11-12). The District Court found that "the references [in Pandya/Nivagen-1] to phosphorus concentrations 2.7 mmol/100 mL or lower and 5.5 mmol/100 mL or lower refute [Petitioner's] claim that the '661 patent's disclosure of a phosphorus concentration as low as 1.5 mmol/100 mL constitutes new matter." (*Id.* at 11). As explained above, the decision of the District Court is correct and supported by Federal Circuit law.

Turning next to the overlap with Grounds II and III, at the District Court, Petitioner argued that the Fresenius Kabi product labeling (the "FK PI") disclosed all elements of representative '661 patent claims 3 and 13 (including the concentration of the nutrients to be administered to patients) *except* (a) the pH limitations, and (b) and the use of a flexible package or flexible polyolefin package. (Ex. 2017 (Opposition Brief) at 11). Petitioner relied on the same Dr. Amiji to explain that the pH elements clearly missing from the FK PI would somehow be

inherent and that the packaging elements would be a matter of design choice. (*Id.* (quoting and citing to Ex. 2026 (Amiji District Court Declaration) at ¶¶134-136)).

These are precisely the same arguments that Petitioner advances here with regard to the CMP Art, with Terlevich and/or Nevakar now providing the packaging disclosures. While Petitioner may be relying on ostensibly different prior art, it advances identical arguments supported by the same declarant. But the District Court already determined that Petitioner's arguments concerning substantially the same prior art were unpersuasive and ruled that, with respect to Petitioner's obviousness attack, the sterility and ready-to-use properties of the patented invention alone make it more likely than not that the claims are not obvious over the FK PI. (Ex. 2003 at 10). This ruling applies squarely against the same arguments being raised again here as Grounds II and III.

Petitioner's reference to Terlevich (Ex. 1009) does not change this analysis. Although Petitioner characterizes Terlevich as "explaining" "RTU solutions are easier to administer ...," and "[a] RTU solution also helps avoid unnecessary calculations, and potential errors, by practitioners," Petitioner was careful not to label the dilute solution in Phosphate Polyfusor® disclosed in Terlevich as a "sterile, RTU" product. (Petition at 22-23, 36-37). Indeed, as Dr. Rabinow explains in detail, the Fresenius Kabi PPF product was not a sterile, RTU product and a POSA would know that the PPF product, which employs an open, contamination-prone system

requiring a vent that connects the contents of the semi-rigid container to the ambient air before the contents could be properly infused into a patient, was indeed the *opposite* of a sterile, RTU product employing a closed system, which is what the '661 patent claims. *See supra* Section II.C. Ample prior art references, presented and analyzed by Dr. Rabinow, clearly show that an open system like the PPF product required a pre-infusion step of opening the container and exposing the contents to ambient air, so it was not a closed system like the sterile RTU product claimed in the '661 patent. (Ex. 2006 at ¶¶31-45). Because of the open connection to outside air, harmful contaminants were frequently observed to be present in the nutrient solution after the container was opened. (*Id.*).

Accordingly, Petitioner shied away from using Terlevich as its primary reference. For Ground II, the CMP Art (which discloses a *concentrate* product and is similar to the FK-PI art Petitioner used in the parallel litigation) is the primary reference Petitioner relies on for its attempt to invalidate the '661 patent. (*See* Petition at 34-61). Ground III of the Petition is based on “the Ground 2 Art and Nevakar,” which means the CMP Art is taking the lead again. (*Id.* at 61-69). Therefore, Petitioner is making here the same patent obviousness argument it has already made, and lost on, in the parallel litigation. (Ex. 2003 at 9-10). The argument is that a POSA could start from a potassium phosphates concentrate commercial product (be it from “CMP” or “FK” company) and figure out the dilution

and the packaging to use, arriving at the sterile, RTU potassium phosphates product claimed in the '661 patent. The argument is identical here and in the parallel litigation.

For the foregoing reasons, this factor strongly favors Nivagen and supports denial of institution.

5. Factor 5: Petitioner and Defendant Relationship

Amneal, this Petitioner, is the defendant in the parallel District of Delaware action. Accordingly, this factor favors Nivagen and supports denial of institution.

6. Factor 6: Any Other Factors to Consider

As Nivagen's forthcoming Preliminary Response will confirm, the Petition fails even to meet Petitioner's threshold burden for institution, let alone demonstrate "compelling merits," a determination that, in any event, could not overcome the other factors in the Board's discretionary denial analysis. Guidance on USPTO's rescission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation," (Mar. 24, 2025) ("compelling merits alone is not dispositive in making the [*Fintiv*] assessment").

Finally, Amneal states in its Petition that it "hereby stipulates under *Sotera* that, if this IPR is instituted, Petitioner will not pursue any grounds raised in this Petition, or any grounds Petitioner could have reasonably raised in this Petition, in the Litigation or any parallel proceeding." Petition at 12. However, Amneal's

litigation counsel never responded to Nivagen’s inquiry of a *Sotera* stipulation in the parallel litigation, and has not filed such a stipulation in Court. (Ex. 2024 (counsel email); Ex. 2015 (no such stipulation has been entered)). Until that stipulation is filed, and it must happen before the Board institutes this IPR, Amneal’s statement in the Petition lacks the formality and finality of a stipulation.

Furthermore, while such a stipulation can be relevant, it is no longer dispositive. Instead, the Board considers the *Sotera* stipulation along with all other factors, holistically. The Board may take into consideration that Petitioner has already presented the same patent anticipation defense and a very similar patent obviousness defense in Court, and the Court found that Petitioner did not even raise a substantial question on patent invalidity as explained above. Therefore, a *Sotera* stipulation by Petitioner, even when it is properly filed, still represents an attempt by Petitioner to have a second bite at the apple, to try its luck again—this time before the Board. Instead of achieving efficiency and *preventing* duplication, Petitioner is seeking to do the opposite, to *create* duplication by urging the institution of the IPR. Petitioner has *already* advanced in a fully-briefed and carefully-considered preliminary injunction proceeding “the grounds raised in this Petition, or reasonably could have raised in this Petition,” but failed to convince the Court under a lenient “substantial question” standard. Petitioner is now trying to get another chance under the “preponderance of evidence” standard before the Board, which is still preferable

for Petitioner than proving patent invalidity under the “clear and convincing” standard at trial. In its effort to try again, however, Petitioner is essentially asking the Board to redo the work the District Court has already done.

In sum, the factors enumerated in the Board’s precedential *Fintiv* decision favor denial of institution, and Petitioner has not met its § 314(a) burden—a burden that never shifts to Patent Owner—to show that institution should be granted. The Board should exercise its discretion to deny institution here to give effect to the intent of Congress (reflected in *Fintiv*) that IPR proceedings be a “‘true alternative’ to . . . district court proceeding[s],” *Motorola Solutions, Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (P.T.A.B. Mar. 28, 2025), and to “improve PTAB efficiency [and] maintain PTAB capacity to conduct AIA proceedings.” “Interim Processes for PTAB Workload Management” at 3 (March 26, 2025).

IV. INSTITUTION SHOULD BE DENIED UNDER THE DIRECTOR’S MEMORANDUM

The factors set forth in the Director’s March 26th Memorandum underscore that denial of institution is appropriate here. First, as discussed above, the District Court already preliminarily adjudicated the validity of the challenged patent claims under a standard that is more lenient to Petitioner, and the prosecution history demonstrates the weakness of Petitioner’s unpatentability challenge.

Additionally, Petitioner relies heavily on expert testimony to fill gaps in the prior art. Specifically, Petitioner relies almost exclusively on Dr. Amiji with respect

to the limitations of dependent claims 6 through 8, which recite specific stability parameters after autoclaving and storage. Petition at 52-55 (heavily relying on Declaration of Dr. Amiji (Ex. 1003) at ¶¶260-272).

Furthermore, the Director’s “determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented” and the Director has denied institution where, as here, there has been meaningful investment in the parallel proceeding by the parties. *See, e.g., Biofrontera Inc., et al. v. Sun Pharmaceutical Industries, Inc.*, IPR2025-002876, Paper 10 (P.T.A.B. Jul. 2, 2025).

V. CONCLUSION

For the foregoing reasons, institution should be denied.

CERTIFICATION OF WORD COUNT 37 C.F.R. § 42.6(e)

Pursuant to 37 C.F.R. §42.24(d), Patent Owner hereby certifies that the word count for the foregoing PATENT OWNER’S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION is 6182 words, which is within the limit set in 37 C.F.R. §42.24(b)(1). This word count does not include the table of contents, table of authorities, exhibit list, certificate of word count, and certificate of service. This word count was prepared using Microsoft Word.

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CERTIFICATE OF SERVICE

The undersigned certifies that on July 17, 2025, a complete and entire copy of this Patent Owner's Brief in Support of Discretionary Denial was provided by email to the Petitioner by serving the correspondence address of record as follows:

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