

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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
BRIEF IN SUPPORT OF DISCRETIONARY DENIAL**

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1006	U.S. Patent Application Publication No. 2022/0110969 ("Nivagen-1" or "the '001 application")
1007	International Patent Application Publication No. WO2020/081118 ("CMP-PCT")
1008	Federal Drug Administration Drug Label for "POTASSIUM PHOSPHATES injection, for intravenous use," September 2019
1009	Terlevich, A., et al. "Refeeding syndrome: effective and safe treatment with Phosphates Polyfusor." <i>Alimentary pharmacology & therapeutics</i> 17.10 (2003): 1325-1329 ("Terlevich") https://doi.org/10.1046/j.1365-2036.2003.01567.x
1010	Ogawa, T., Miyajima, M., Wakiyama, N. and Terada, K., 2013. Effects of phosphate buffer in parenteral drugs on particle formation from glass vials. <i>Chemical and Pharmaceutical Bulletin</i> , 61(5), pp.539-545. ("Ogawa") https://doi.org/10.1248/cpb.c12-01025
1011	U.S. Patent Application Publication No. 2019/0290602 ("Nevakar")
1012	Sealed Air Product Data Sheet for Nexcel® M312 Film
1013	Nema, S. and Ludwig, J.D. eds., 2010. <i>Pharmaceutical Dosage Forms: Parenteral Medications</i> , Third Edition, Volume 1: Formulation and Packaging, 2010 Informa Healthcare, CRC Press. Chapters 5 and 12 ISBN-13: 9781420086430

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1014	Rowe, Raymond C., Paul Sheskey, and Marian Quinn. "Handbook of Pharmaceutical excipients," pp. 637-40, 656-661 (2009) ISBN: 9781582121352
1015	ISMP Canada Safety Bulletin, Volume 6, Issue 2 April 25, 2006, Safety Strategies for Potassium Phosphates Injection https://web.archive.org/web/20061009113956/http://www.ismp-canada.org/download/ISMPCSB2006-02PotassiumPhosphates.pdf
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1018	Drug Administration, Orange Book, Prescription and Over-the-Counter Drug Product List, 39TH EDITION, Cumulative Supplement Number 09: September 2019, ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST https://web.archive.org/web/20191215034819/https://www.fda.gov/media/131880/download
1019	Brunelli, S.M. and Goldfarb, S., 2007. Hypophosphatemia: clinical consequences and management. Journal of the American Society of Nephrology, 18(7), pp.1999-2003.
1020	Redline comparison of the text of US2022/0110969 and US2023/0405045
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1023	Declaration of Mina Ching from the Internet Archive (archive.org)
1024	Declaration of Dr. Sylvia Hall-Ellis, Ph.D.
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1026	Wadsworth, R.L. and Siddiqui, S., 2016. Phosphate homeostasis in critical care. <i>Bja Education</i> , 16(9), pp.305-309.
1027	Pages 4-16 of Exhibit 1023, i.e., the September 23, 2020, Internet Archive of the WebSite https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2c2078d1-9edc-4d0c-a72a-5491c28a5aac
1028	<i>Ex Parte Shirley</i> , Appeal No. 2009-2352, (B.P.A.I. May 14, 2009),
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1030	Perks, W., Iazzetta, J., Chan, P.C., Brouzas, A., Law, S. and Walker, S.E., 2017. Extended stability of sodium phosphate solutions in polyvinyl chloride bags. <i>The Canadian Journal of Hospital Pharmacy</i> , 70(1), p.7-12.
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1042	Scheduling Order entered in <i>Identitii Limited v. JPMorgan Chase & Co.</i> , No. 23-cv-01095 (D. Del.), dated July 21, 2025

I. INTRODUCTION

Petitioner hereby submits this opposition to Patent Owner's Brief In Support of Discretionary Denial ("PO-Brief"). There are compelling reasons why *inter partes* review of the '661 patent is an appropriate use of Office resources and the Petition should not be discretionarily denied.

First, the Examiner erred in issuing the '661 patent. As explained in the Petition, the '661 patent is a continuation-in-part, and the Examiner failed to realize that the '661 patent's parent application, which published more than a year prior to the effective filing date of the '661 patent, anticipated and rendered obvious all claims of the '661 patent. (Petition at 4-13, 24-34.)

Second, there are no settled expectations. The '661 patent was filed in September 2023 and issued on March 12, 2024. It was therefore not IPR eligible until December 13, 2024. Petitioner challenged the '661 patent within four months of it being IPR eligible.

Third, the litigation is at a standstill and Patent Owner has made no meaningful effort to advance the litigation. Indeed, as of the filing of this Opposition—more than one year after filing the Complaint—a schedule has not been entered by the Court, and Patent Owner has not asked for one.

Fourth, the art and arguments are new. The Examiner issued a first action allowance mentioning only a single reference (Koneru), and the Petition does not

apply Koneru. Indeed, it cannot be said that the prosecution record overlaps with the art and arguments raised in the Petition because the Examiner allowed the claims without issuing a prior art rejection—the prior art and arguments of the Petition are new in every material way.

For these and the other reasons stated herein, the Office should not discretionarily deny the Petition.

II. THE PATENT EXAMINER ERRED IN GRANTING THE CIP '661 PATENT OVER ITS PARENT APPLICATION

As explained in the Petition, the '661 patent was filed as application no. 18/460,941 (“the '941 application”) on September 5, 2023. (Petition at 4.) The '661 patent is a continuation-in-part (CIP) of patent application no. 17/499,001 (“the '001 application”) filed October 12, 2021, which published as U.S. Patent App. Pub. No. 2022/0110969, on April 14, 2022, i.e., more than one year prior to the effective filing date of the '661 patent. (Petition at 4, 21.)

Apparently recognizing that the claim scope of its parent application was inadequate, the '661 patent was *broadened* to describe and claim a wider range of phosphorous. Specifically, the specification and claims of the '661 patent were broadened to recite 1.5-15 mmol/100 mL of phosphorus versus only 15 mmol/100 ml of phosphorous in the parent application:

Concentration of phosphorous in Petitioner's product	Claimed concentration of phosphorous in the parent application (i.e., the '001 application)	Claimed concentration of phosphorous in the '661 patent
<u>6 mmol/ 100 ml</u> of phosphorous	Claim 1: “wherein the solution comprises <u>15 mmol/100 ml</u> phosphorus” Claim 11: “a potassium phosphates in an aqueous sodium chloride solution containing ... (b) about <u>15 mmol/100 ml</u> phosphorus....” Claim 17: “wherein the solution comprises about <u>15 mmol/100 ml</u> phosphorus....”	Claim 1: “wherein the solution comprises <u>between 1.5 mmol/100 ml and 15 mmol/100 ml</u> phosphorous” Claim 11: “a potassium phosphates in an aqueous sodium chloride solution containing ... (b) <u>between about 1.5 mmol 100 ml and 15 mmol/100 ml</u> phosphorus....” Claim 17: “wherein the solution comprises <u>between 1.5 mmol/100 mL and 15 mmol/100 ml</u> phosphorus....”

(Ex-2017 at 11 (explaining the phosphorous concentration of Amneal's commercial product is 6 mmol/100 ml).)

As explained in the Petition, the parent application (i.e., Nivagen-1) fails to provide written description support for at least the broadened phosphorus range of the '661 patent. (Petition at 5-13; Ex-1020 (showing changes to the specification of the '661 patent relative to the parent application, including the new phosphorous range).) Thus, the Examiner erred in granting the '661 patent over the parent application because the parent application does not support the claimed range of

“between 1.5 mmol/100 ml and 15 mmol/100 ml phosphorous;” but the parent application does disclose an endpoint of the claimed range (15 mmol/100 ml), thereby anticipating or rendering obvious the claims of the '661 patent. (Petition at 24-34.) Examiner error counsels in favor of not discretionarily denying an IPR. *CSPC Pharma. Group. Ltd., v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11, July 16, 2025 (discretionary denial inappropriate when Examiner erred “in a manner material to the patentability of the challenged claims by not considering or overlooking specific teachings in” the cited prior art), *Anthony Inc. v. ControlTec, LLC*, IPR2025-00559, Paper 9 (July 16, 2025) (examiner error counsels in favor of referral to the merits panel).

Patent Owner essentially has no rebuttal to Petitioner's showing. Patent Owner first argues that the parent application is listed on the face of the patent. (PO-Brief at 5-6.) However, Patent Owner did not file an Information Disclosure Statement listing the parent application and there is no evidence that the Examiner considered the parent application during prosecution beyond terminal disclaimer purposes. (Ex-1002 at 66-67 (IDS filed by Patent Owner fails to list the parent application).) Indeed, Patent Owner's filing of the terminal disclaimer before prosecution even started appears to have been an effort to avoid having the Examiner consider the parent application. (Ex-1002 at 81-92 (Terminal Disclaimer filed November 23, 2023, i.e., months before the first and only action was issued by the

Examiner).) By filing a terminal disclaimer when no double patenting rejection existed, Patent Owner sought (and was successful) in avoiding an evaluation of the content of the parent application.

Patent Owner's remaining argument proves that the '661 patent's claims are unsupported by the parent application. Specifically, Patent Owner concedes that the parent application fails to disclose the lower limit of the claimed phosphorous range. (PO-Brief at 6-7.) Yet, as explained in the Petition, written description support cannot be based on what is obvious. (Petition at 12.) Further, as explained in the Petition, the two ranges cited in Patent Owner's brief (i.e., "not more than 2.7 mmol/100 ml" or "not more than 5.5 mmol/100 ml") do not and cannot provide written description support. (Petition at 8-11.)

In sum, the Examiner erred by failing to consider how the specification of the '661 patent changed relative to its parent application, whether such changes affected the priority date of the '661 application (they did), and thus whether the '661 patent's parent application anticipated or rendered obvious the claims of the '661 patent (it does).

III. THE *FINTIV* FACTORS DO NOT FAVOR DISCRETIONARY DENIAL

The Director should decline to exercise discretion under 35 U.S.C. §314(a) because efficiency, fairness, and the merits support institution. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) (precedential) ("*Fintiv*"). Each

Fintiv factor is addressed below. Five factors weigh against discretionary denial and the remaining factor is neutral. Thus, discretionary denial is unwarranted.

A. Factors 1 and 2 Strongly Weigh Against Denial.

Factor 1 considers whether a stay exists or is likely to be granted if a proceeding is instituted, and Factor 2 considers the proximity of the district court's trial date to the Board's projected statutory deadline. *Fintiv*, IPR2020-00019, Paper 11 at 6-9. Below, Petitioner first addresses Factor 2 as it informs the analysis of Factor 1.

First, the underlying litigation in the District of Delaware is at a standstill. Patent Owner filed a motion to dismiss certain of Petitioner's counterclaims, and briefing on that issue concluded about 6 months ago. Judge Williams has not acted on the motion and Patent Owner has taken no steps before Judge Williams to obtain a ruling. Even assuming *arguendo* Judge Williams acted on the motion to dismiss and the parties agreed to a scheduling order, a trial is unlikely to occur until 2028, i.e., ***more than a year after*** the final written decision would be due in this IPR.¹

¹ A Notice of Filing Date Accorded issued May 20, 2025. An institution decision is therefore due by November 20, 2025, and a final written decision is due November 20, 2026.

Specifically, in similarly situated cases (with a preliminary injunction proceeding), Judge Williams typically schedules a trial about two years following entry of the scheduling order. *See SmartSky Networks, LLC v. Gogo Business Aviation, LLC*, No. 22-cv-00266 (D. Del.) (scheduling order entered on February 24, 2023, setting a trial date for April 14, 2025) (Ex-1039); *see also Biogen Inc. v. Sandoz Inc.*, No. 22-cv-01190 (D. Del.) (scheduling order entered on August 25, 2023, setting trial date for May 5, 2025) (Ex-1040). ***No scheduling order*** has been entered in the litigation, and none is forthcoming. Moreover, Judge Williams is currently entering scheduling orders with trials set for 2028. *See Virility Medical Ltd. v. Morari, Inc.*, No. 25-cv-00338 (D. Del.) (scheduling order entered July 16, 2025, setting trial for January 19, 2028) (Ex-1041); *see also Identitii Limited v. JPMorgan Chase & Co.*, No. 23-cv-01095 (D. Del.) (scheduling order entered July 21, 2025, setting trial for February 21, 2028) (Ex-1042). Thus, case law shows that a trial in the litigation is unlikely to occur until at least 2028. Historical statistics confirm that a trial is unlikely to occur until 2028. (Ex-1038 (showing Judge Williams' average and median time to Jury Trial are 33.5 and 41 months, respectively).) Thus, Factor 2 weighs strongly in favor of denying Patent Owner's request. *Snap, Inc. v. SRK Tech. LLC*, IPR2020-00819, Paper 15 at 9 (Oct. 21, 2020) (*precedential*).

Patent Owner argues without evidence Factor 2 favors denial because, if institution is denied, the “time to trial will be short” due to a preliminary injunction proceeding. (PO-Brief at 18.) Patent Owner’s speculative argument should be rejected. *Snap*, IPR2020-00819, Paper 15 at 9 (what a district court would do if institution were denied amounts to “unfounded speculation as to how the court might proceed.”). Further, as shown above, even with a preliminary injunction, time to trial is more than 2 years.

Second, as for Factor 1, a stay is highly likely if an IPR is instituted because Judge Williams routinely grants a stay in view of an instituted IPR. (Ex-1016 at 20 (showing Judge Williams grants a stay about 70% of the time).) Thus, Factor 1 also weighs strongly in favor of denying Patent Owner’s request. *Snap* IPR2020-00819, Paper 15 at 9 .

Patent Owner argues that Factor 1 weighs in favor of discretionary denial because Petitioner has not yet requested a stay and Patent Owner will oppose any stay. (PO-Brief at 17-18.) Again, Patent Owner provides mere speculation and such speculation is inconsistent with Judge Williams’ track record for granting stays. As explained previously, Judge Williams routinely grants a stay in view of an instituted IPR (even if opposed) and there is no reason to believe a stay would not be granted here if an IPR is instituted. Further, it is premature to request a stay given the pending motion to dismiss. If this IPR is instituted, Petitioner will seek a stay and

Judge Williams is very likely to grant Petitioner's motion.

Accordingly, *Fintiv* Factors 1-2 strongly weigh against discretionary denial.

B. Factor 3 Weighs Against Denial.

Factor 3 considers the investment in the parallel proceeding by the court and the parties. *Fintiv*, IPR2020-00019, Paper 11 at 9-12. “This investment factor is related to the trial date factor, in that more work completed by the parties and court in the parallel proceeding tends to support the arguments that the parallel proceeding is more advanced, a stay may be less likely, and instituting would lead to duplicative costs.” *Id.* at 10. As part of this factor, the Office may consider whether the district court has issued a claim construction order or other substantive orders related to the patent-at-issue in the petition. *See id.* at 10, 10 n.17.

This factor favors Petitioner. Although briefing was completed on a preliminary injunction issue, Judge Williams specifically noted “all findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits.” (D.I. 61 at 10) (quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001)). Further, since the Court's order on the preliminary injunction—which was ultimately dissolved—the Court has not invested in the litigation. Petitioner has filed an answer and counterclaims in response to the Complaint, and Patent Owner has moved to dismiss certain of Petitioner's counterclaims. Briefing on Patent Owner's motion to dismiss

concluded nearly six (6) months ago, on February 21, 2025, and there has been no litigation activity since that time.

As the Director has repeatedly recognized, a small amount of investment in a parallel proceeding (as here) is “outweighed by the early challenges to [] patents. ... Early challenges favor robust, predictable patent rights and weigh against discretionary denial.” *Resmed Corp. v. Cleveland Med. Devices Inc.*, IPR2025-00246, Paper 10, June 12, 2025 at 2; *see also Shenzhen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.*, IPR2025-00438, Paper 10, July 17, 2025 at 2. Further, Petitioner expeditiously filed its Petition within a few months of the '661 patent being IPR eligible, which further counsels against discretionary denial.² *Micron Technology, Inc. v. Yangtze Memory Tech. Co., Ltd.*, IPR2025-00117, Paper 19 at 12-13 (*Fintiv* factor 3 weighs against denial even with “a non-trivial level of effort” expended in the district court because of the petitioner’s “expeditious filing of the Petition”).

Thus, Factor 3 also favors Petitioner.

C. Factor 4 Weighs Against Denial.

Factor 4 considers the overlap between issues raised in the petition and in the parallel proceeding. *Fintiv*, IPR2020-00019, Paper 11 at 12-13. This factor favors

² The '661 patent was not eligible for an IPR challenge until December 13, 2024; the Petition was filed April 12, 2025, i.e., within four months of the IPR eligibility date.

Petitioner. Specifically, as explained below, “the petition includes materially different grounds, arguments, and/or evidence than those presented in the district court,” which weighs against exercising discretion to deny institution. *Id.* Moreover, Petitioner has provided a *Sotera* stipulation stating “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 14.) A *Sotera* stipulation weighs strongly against exercising discretion to deny institution. *Charter Comm. Inc. v. Adaptive Spectrum & Signal Alignment, Inc.*, IPR2025-00087, Paper 14, May 5, 2025, at 14 (“*Charter*”) (finding newly offered *Sotera* stipulation “weighs strongly in favor of not exercising discretion to deny institution”).³

Patent Owner argues Petitioner must file a *Sotera* stipulation with the court to be effective, yet provides no authority in support thereof. (PO-Brief at 24-25.) Petitioner's stipulation in the Petition is binding and effective as *Sotera* stipulations are routinely provided in Petitions and/or letters to opposing counsel and treated as

³ Unlike *Charter*, here, no scheduling order has been entered in the District Court, any potential District Court trial date would occur well after a final written decision is due, a stay is highly likely, and minimal investment has occurred in the litigation, i.e., the *Fintiv* factors here weigh against exercising discretion to deny institution.

binding. *Charter* at 14 (stipulation included in Petitioner's briefing (Paper 11) and accepted by USPTO as being binding). Further, Petitioner shall file any necessary stipulations with the Court once an order on the pending motion to dismiss has issued.

Given Petitioner's *Sotera* stipulation, and the estoppel that will apply upon issuance of a final written decision, there will be minimal or no overlap between the invalidity issues raised in the Petition and those that will be raised before Judge Williams if any claims survive IPR and the litigation proceeds to trial. *See Snap*, IPR2020-00820, Paper 15 at 13-16. Nonetheless, Patent Owner argues the overlap between the Petition and the invalidity challenges in the preliminary injunction proceeding weigh in favor of discretionary denial. Not so.

Initially, there is no overlap between the single prior art reference the Court considered during the preliminary injunction, i.e., the Fresenius Kabi product labeling ("FK PI") and Grounds 1-3 in the Petition. Ground 1 is based on the parent application to the '661 patent, Ground 2 is based on the CMP Art in view of Terlevich, optionally in view of Ogawa, and Ground 3 adds Nevakar to the Ground 2 art. (Petition at 3.) In the preliminary injunction order, the Court explained that it was not persuaded that FK PI likely rendered the claims invalid as obvious because of the "sterility and ready-to-use properties of the patented invention." (D.I. 61 at 10.) In contrast, as explained in the Petition, CMP-PCT discloses concentrated

sterile, isotonic solutions in rigid containers, Terlevich discloses ***ready-to-use*** solutions in another type of container (semi-rigid), and it was obvious to prepare ready-to-use versions of CMP-PCT's sterile, isotonic solutions and seal/store those solutions in a ready-to-use container, as per Terlevich. (Petition at 35-37.)

Finally, while some overlap exists with respect to Ground 1 and the arguments raised in the preliminary injunction proceeding regarding anticipation based on the '661 patent's parent application, as the Court noted "all findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." (D.I. 61 at 10 (citations omitted)). Even without Judge Williams' explicit finding, it is well-established that "any finding of fact and conclusions of law made at the preliminary [injunction] stage are of no binding effect whatsoever." *Clark v. K-Mart Corp.*, 979 F.2d 965, 969 (3d Cir. 1992) (citing *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395-96 (1981)). In any event, such overlap may benefit the district court's analysis of what remains. *Snap*, IPR2020-00820, Paper 15 at 13-16.; *MED-EL Elektromedizinische Geräte GmbH v. Sonova AG*, IPR2020-00176, Paper 13 at 15 (P.T.A.B. June 3, 2020) (overlap "may inure to the district court's benefit ... by simplifying issues for trial").

Thus, *Fintiv* factor 4 weighs against discretionary denial.

D. Factor 5 Is Neutral.

Factor 5 considers whether the parties are the same. *Fintiv*, IPR2020-00019,

Paper 11 at 13-14. This factor is neutral as the parties here are the same as in the litigation. *Snap*, IPR2020-00820, Paper 15 at 16.

E. Factor 6 Weighs Against Denial.

Factor 6 considers “other circumstances” that impact discretionary denial, such as the merits of the petition. *Fintiv*, IPR2020-00019, Paper 11 at 14-16. This factor strongly favors Petitioner.

First, Petitioner challenged the '661 patent within four months of its IPR eligibility date. This weighs strongly in favor of not discretionarily denying the Petition. *Resmed Corp. v. Cleveland Med. Devices Inc.*, IPR2025-00246, Paper 10, June 12, 2025 at 2; *see also Shenzhen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.*, IPR2025-00438, Paper 10, July 17, 2025 at 2.

Second, Petitioner's challenge is strong. The '661 patent is not entitled to claim priority to its parent application, and its parent application anticipates and/or renders obvious all claims of the '661 patent as shown in Ground 1. (Petition at 24-34.) Further, the same art and arguments provided in Grounds 2-3 were not considered by the Examiner, and that prior art discloses the phosphorous concentration that the Examiner thought was missing from the prior art. (Ex-1002 at 26 (Examiner's Reasons for Allowance).)

Third, as the Petition shows, the prior art discloses, teaches and suggests each and every limitation of the Challenged Claims, i.e., “expert testimony, common

sense, and other evidence” are not being “used to supply a missing claim limitation.”

(*Enforcement and Non-Waiver of 37 C.F.R. § 42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews*, July 31, 2025, at 1.) Indeed, Patent Owner can only point to dependent claims 6 and 8 as allegedly relying “heavily” on Petitioner’s expert’s testimony, effectively conceding that the prior art and arguments of the Petition read on all other claims, including all independent claims. (PO-Brief at 26-27.) As the Supreme Court held in *SAS*, an IPR shall be instituted if even one claim is shown to be unpatentable. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018). Moreover, Patent Owner is wrong—the prior art discloses “stability parameters for autoclaving and storage,” and Petitioner’s expert’s testimony is simply used to show a reasonable expectation of success. (Petition at 52 (prior art disclosures of particulate count stability), 53-54 (autoclaving prior art), 54 (prior art disclosures of chemical stability).)

In sum, five *Fintiv* factors favor Petitioner and one is neutral. Accordingly, discretionary denial under 35 U.S.C. §314(a) is unwarranted.

IV. THE SAME ART AND ARGUMENTS HAVE *NOT* ALREADY BEEN CONSIDERED

A. The Ground 1 Art Has Not Been Considered

As explained in §II, *supra*, the Examiner did not consider the Ground 1 art, i.e., the ’661 patent’s parent application—Nivagen-1. No information disclosure statement listed the parent application, and Patent Owner prematurely filed a

Terminal Disclaimer statement in an apparent effort to avoid evaluation of the disclosures of the parent application by the Office.

B. The Examiner Erred in Failing To Reject the '661 Patent's Claims Based on Its Parent Application

As also explained in §II, *supra*, the Examiner failed to consider how the specification of the '661 patent changed relative to its parent application, whether such changes affected the priority date of the '661 application (they did), and thus whether the '661 patent's parent application anticipated or rendered obvious the claims of the '661 patent (it does). In other words, *Becton* factors (a), (b) and (d) favor Petitioner—the Ground 1 art is different, the arguments are different, and there is no overlap in any of the art or arguments, nor could there be as the Examiner issued a first action allowance. For this reason alone, the same art and arguments have not been presented to the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential) at 7. (“Under [35 U.S.C.] § 325(d), the art and arguments must have been previously presented to the Office during proceedings pertaining to the challenged patent.”)

Further, the Examiner materially erred in granting the '661 patent over its parent application because the parent application anticipates and renders obvious all claims of the '661 patent, which further counsels in favor of not discretionarily denying the Petition. *Id.* at 10-11. As per the *Becton* factors, the Ground 1 art was

not evaluated during examination and did not form the basis for any rejection (factor (c)), Petitioner has explained how the Examiner erred (factor (e)), and the evidence in the Petition warrants reconsideration because the parent application to the '661 patent anticipated and renders obvious the claims of the '661 patent (factor (f)). *Id.* at 10.

For at least these reasons, discretionary denial under §325(d) is unwarranted.

C. The Ground 2-3 Art and Arguments Have Not Been Considered

Petitioner's Grounds 2-3 rely on prior art that applies irrespective of the priority date of the '661 patent. The Office has also not considered this art or the arguments presented in the Petition.

Specifically, Ground 2 is based on the CMP Art in view of Terlevich, optionally in view of Ogawa, while Ground 3 adds Nevakar. (Petition at 3.) As Patent Owner concedes, none of this prior art, except for CMP-PCT, was before the Examiner during prosecution. (PO-Brief at 7-8.) And while Patent Owner goes to great lengths to prove CMP-PCT is the same reference cited in the background of its patent (i.e., U.S. Patent No. 10,632,150 to Thomas⁴), Petitioner already explained as much in the Petition. (Petition at 22, n.11.) Thus, Patent Owner's contention that

⁴ The '661 patent incorrectly refers to Thomas as "U.S. Ser. No. 10/632,150." (Ex-1001 at 2:49-50.) The serial number for Thomas is 16/389,181, while its patent number is 10,632,150.

Petitioner is “recycling the same reference from the prosecution history but under a different title and without any explanation of the differences,” is plainly false. (PO-Brief at 8.)

Patent Owner is also wrong that the Examiner “considered” CMP-PCT. (*Id.* at 7.) The Examiner never cited, relied on or made any arguments regarding CMP-PCT (or any of its related family members) during prosecution—instead a first action allowance issued in which the Examiner cited U.S. Patent No. 11,141,430 to Koneru, not CMP-PCT. (Ex-1002 at 24-26; Petition at 4.)

Patent Owner spends 4 pages arguing the art of Terlevich, Ogawa and Nevakar are “cumulative,” yet Patent Owner cites nothing in the prosecution history in support of its allegation. (PO-Brief at 8-11.) Instead, Patent Owner relies on an expert declaration that attacks the disclosures of the prior art. (*Id.*) This alone proves that the art and arguments have not been before the Office. There would be no need for expert testimony on disputed factual issues if the Office had already considered the art. Indeed, the types of issues raised by Patent Owner's expert declaration are exactly what IPRs were designed to address—whether new, never before considered art and arguments invalidate the challenged claims. 35 U.S.C. §§ 311(b), 325(d). Even if the prior art teachings were merely cumulative (they are not), that means the Examiner necessarily erred by failing to issue any prior art rejections during examination.

Patent Owner's analysis is also inapposite. None of claims 1-8 require a flexible container, yet Patent Owner spends pages arguing why Terlevich fails to disclose this feature.⁵ (PO-Brief at 9-11.) Patent Owner's argument that Koneru (US11,141,430) discloses rigid or non-rigid packing also misses the mark as the Examiner allowed the claims over Koneru due to its phosphorous content, not its packaging disclosures. (PO-Brief at 10-11; Ex-1002 at 26 ("Koneru et al. disclose total phosphorous concentration of about 1mM/mL ... Koneru et al. does not disclose or provide motivation to arrive at 0.15 mM/mL as claimed."); Petition at 4.)

Claims 1-8 require a ready-to-use solution (RTU), which Terlevich discloses, and the combination of the CMP Art and Terlevich render obvious claims 1-8. (Petition at 45-55.) Patent Owner states Terlevich does not disclose a RTU solution, but fails to explain why. (PO-Brief at 7.) Terlevich's solutions clearly are RTU as they are ready to be intravenously administered to a patient without adjustment. (Ex-1001 at 5:43-54 (defining ready-to-use solutions); Petition at 46; Ex-1009-Terlevich at 1326.) Other record evidence corroborates Petitioner's showing that the Terlevich solutions are ready-to-use:

"A commonly used treatment is the Phosphate Polyfusor®, a solution containing 50 mmol PO_4^{3-} , 9.5 mmol K^+ , and 81 mmol Na^+ in 500 ml,

⁵ It is undisputed that Terlevich discloses a semi-rigid container, i.e., at least somewhat flexible container. (PO-Brief at 9.)

given over 24 h via a central venous catheter. This preparation should be infused alone, via a dedicated port of a central line, and if given peripherally should have a dedicated cannula.”

(Ex-1026 at 309; Petition at 16, 36, 40.) Indeed, while Patent Owner's expert improperly conflates sterility and ready-to-use, he also implicitly admits the Terlevich solutions were ready-to-use. (Ex-2006 at ¶27 (container only needs to be opened for solution to be administered); *id.* at ¶¶2, 19-20, 45 (always tying “sterile” to “ready-to-use”).) For at least these reasons, the art and arguments with respect to Grounds 2-3 are new.

Patent Owner also misunderstands Petitioner's argument by arguing irrelevant facts such as sterility and isotonicity, and how open air might “potentially have a detrimental effect” on those properties. (PO-Brief- at 7-8.) Petitioner's argument is simple: the CMP Art discloses concentrated sterile, isotonic solutions in rigid containers and Terlevich discloses ready-to-use solutions in another type of container (semi-rigid), and it was obvious to prepare ready-to-use versions of the CMP Art's sterile, isotonic solutions and seal/store those solutions in a ready-to-use container, as per Terlevich. (Petition at 35-37.) Sterility and tonicity are unaffected in the combination.

In sum, the art and arguments presented in Grounds 2-3 of the Petition were not previously before the Office, and discretionary denial under §325(d) is unwarranted.

V. **CONCLUSION**

As shown herein, discretionary denial is unwarranted. The challenged patent is new (no settled expectations), a District Court trial date is unknown, a stay is likely, and the Examiner erred by failing to analyze the priority date of the '661 patent and the invalidating disclosures of its parent application. Moreover, five of the *Fintiv* factors favor Petitioner while the remaining *Fintiv* factor is neutral. Finally, art and arguments of Grounds 1-3 have not previously been considered by the Office. Accordingly, Petitioner respectfully requests referral of the Petition to the merits panel.⁶

⁶ Petitioner notes this opposition is timely as it was filed “within 1 month after the due date for the patent owner discretionary denial brief.” *See Interim Director Discretionary Process* (“A brief opposing a patent owner’s discretionary denial request must be filed by the petitioner ***within one month after the due date for the patent owner discretionary denial brief, which is typically the POPR due date.***”) (<https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>); and “*FAQs for Interim Processes for PTAB Workload Management*,” Item No. 7 (“The timing will not change if a patent owner files its discretionary denial brief early. A petitioner opposition will be due within 1 month of the due date for a patent owner discretionary denial brief (i.e., on the POPR due date)....”).) [CONTINUED]

Patent No. 11,925,661
IPR2025-00731

Petitioner's Opposition Brief

Respectfully submitted,
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(<https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>).

CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of this paper (*PETITIONER'S OPPOSITION TO PATENT OWNER'S BRIEF IN SUPPORT OF DISCRETIONARY DENIAL*) and its accompanying exhibits have been served by emailing counsel of record for Patent Owner, identified below, by emailing shashank@ipfdalaw.com, brent@ipfdalaw.com, and yixin@ipfdalaw.com.

Respectfully submitted,
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Date: August 20, 2025

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