

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, INC.,
Petitioner

v.

NIVAGEN PHARMACEUTICALS, INC.
Patent Owner.

IPR2025-00779
Patent No. 11,813,291

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

TABLE OF CONTENTS

TABLE OF EXHIBITS	v
I. INTRODUCTION	1
II. THE <i>FINTIV</i> FACTORS DO NOT FAVOR DISCRETIONARY DENIAL.....	2
A. Factors 1 and 2 Strongly Weigh Against Denial.....	2
B. Factor 3 Weighs Against Denial.	5
C. Factor 4 Weighs Against Denial.	7
D. Factor 5 Is Neutral.....	9
E. Factor 6 Weighs Against Denial.	9
III. THE SAME ART AND ARGUMENTS HAVE <i>NOT</i> ALREADY BEEN CONSIDERED	11
IV. CONCLUSION.....	16
CERTIFICATE OF SERVICE	19

TABLE OF AUTHORITIES

	Page(s)
Federal Cases	
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (Mar. 20, 2020)	2, 5, 7, 9
<i>Biogen Inc. v. Sandoz Inc.</i> , No. 22-cv-01190 (D. Del.) (scheduling order entered on August 25, 2023, setting trial date for May 5, 2025)	3
<i>Charter Comm. Inc. v. Adaptive Spectrum & Signal Alignment, Inc.</i> , IPR2025-00087, Paper 14, (May 5, 2025)	7, 8
<i>Identitii Limited v. JPMorgan Chase & Co.</i> , No. 23-cv-01095 (D. Del.) (scheduling order entered July 21, 2025, setting trial for February 21, 2028)	3
<i>Micron Technology, Inc. v. Yangtze Memory Tech. Co., Ltd.</i> , IPR2025-00117, Paper 19 (2025)	6
<i>Purdue Pharma L.P. v. Boehringer Ingelheim GmbH</i> , 237 F.3d 1359 (Fed. Cir. 2001)	5
<i>Resmed Corp. v. Cleveland Med. Devices Inc.</i> , IPR2025-00246, Paper 10, (June 12, 2025)	6, 9
<i>SAS Inst., Inc. v. Iancu</i> , 138 S. Ct. 1348 (2018)	11
<i>Shenzen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.</i> , IPR2025-00438, Paper 10, (July 17, 2025)	6, 10
<i>SmartSky Networks, LLC v. Gogo Business Aviation, LLC</i> , No. 22-cv-00266 (D. Del.) (scheduling order entered on February 24, 2023, setting a trial date for April 14, 2025)	3
<i>Snap, Inc. v. SRK Tech. LLC</i> , IPR2020-00819, Paper 15 (Oct. 21, 2020)	4
<i>Snap</i> , IPR2020-00820, Paper 15 (2020)	8, 9
<i>Virility Medical Ltd. v. Morari, Inc.</i> , No. 25-cv-00338 (D. Del.) (scheduling order entered July 16, 2025, setting trial for January 19, 2028)	3

Federal Statutes

35 U.S.C. § 311(b)	13
35 U.S.C. § 314(a)	2, 11
35 U.S.C. § 325(d)	13, 16

Regulations

37 C.F.R. § 42.104(b)(4)	10
--------------------------------	----

Other Authorities

https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload- management	17
https://www.uspto.gov/patents/ptab/interim-director-discretionary- process	17
U.S. Patent No. 10,632,150	12
U.S. Patent No. 11,141,430	12

TABLE OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 11,813,291 (the “’291 patent”)
1002	File history for the ’291 patent
1003	Declaration of Dr. Mansoor Amiji
1004	File history for U.S. Patent Application No. 18/460,941
1005	File history for U.S. Provisional Patent Application No. 63/090,518 (“’518-PRV”)
1006	RESERVED
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	RESERVED
1013	Nema, S. and Ludwig, J.D. eds., 2010. <i>Pharmaceutical Dosage Forms: Parenteral Medications, Third Edition, Volume 1: Formulation and Packaging</i> , 2010 Informa Healthcare, CRC Press. Chapters 5 and 12 ISBN-13: 9781420086430

Exhibit	Description
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
1016	Litigation Docket and Statistics for Judge Williams, D. Del.
1017	Federal Drug Administration, NDA approval letter to CMP Development LLC, September 19, 2019 https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/212121Orig1s000ltr.pdf
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	RESERVED
1021	Complaint, <i>Nivagen Pharma. Inc. v. Amneal Pharma. Inc.</i> , C.A. No. 24-846-GBW (D. Del.)
1022	Amended Complaint, <i>Nivagen Pharma. Inc. v. Amneal Pharma. Inc.</i> , C.A. No. 24-846-GBW (D. Del.)
1023	Declaration of Mina Ching from the Internet Archive (archive.org)
1024	Declaration of Dr. Sylvia Hall-Ellis, Ph.D.
1025	RESERVED

Exhibit	Description
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),
1029	Curriculum Vitae of Dr. Mansoor M. Amiji
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.
1031	U.S. Patent No. 4,872,553
1032	U.S. Patent No. 5,881,535
1033	U.S. Patent No. 5,896,989
1034	U.S. Patent No. 6,007,529
1035	U.S. Patent No. 6,713,137
1036	TechnoFlex Website: “PP bags for ready-to-use solution” Available from: https://web.archive.org/web/20180212220920/http://www.technoflex.net/en/produit/pp-bags-for-ready-to-use-medication/
1037	U.S. Patent No. 5,783,269
1038	Docket Navigator statistics for Judge Gregory Williams of the District of Delaware
1039	Scheduling Order entered in <i>SmartSky Networks, LLC v. Gogo Business Aviation, LLC</i> , No. 22-cv-00266 (D. Del.), dated February 24, 2023
1040	Scheduling Order entered in <i>Biogen Inc. v. Sandoz Inc.</i> , No. 22-cv-01190 (D. Del.), dated August 25, 2023
1041	Scheduling Order entered in <i>Virility Medical Ltd. v. Morari, Inc.</i> , No. 25-cv-00338 (D. Del.), dated July 16, 2025
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 '291 patent is an appropriate use of Office resources and the Petition should not be discretionarily denied.

First, there are no settled expectations. The '291 patent was filed in September 2021 and issued on November 14, 2023. It was therefore not IPR eligible until August 15, 2024. Petitioner challenged the '291 patent within eight months of it being IPR eligible.

Second, 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.

Third, 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 *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

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

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.

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 16.) 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 15-16.) 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 eight months of the '291 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”).

² The '291 patent was not eligible for an IPR challenge until August 15, 2024; the Petition was filed April 11, 2025, i.e., within eight months of the IPR eligibility date.

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 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 5-6.) 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

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.

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 21-22.) 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 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 1-2 in the Petition. Ground 1 is based on the CMP Art in view of Terlevich and Perks, optionally in view of Ogawa, and Ground 2 adds Nevakar to the Ground 2 art. (Petition at 4.) 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 16-18.)

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 '291 patent within eight 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 Shenzen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.*, IPR2025-00438, Paper 10, July 17, 2025 at 2.

Second, Petitioner's challenge is strong. The art and arguments provided in Grounds 1-2 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 152 (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.) Patent Owner's arguments regarding reliance on expert testimony do not demonstrate otherwise (PO-Brief at 23-24.) The Challenged Claims are directed to a "solution," and Patent Owner admits that Perks discloses the claimed phosphorous concentration. (*Id.*) Thus, Patent Owner's arguments regarding the prior art teachings how to arrive at the claimed concentration are unavailing. Further, Patent Owner's arguments regarding the "flexible" container limitations in dependent claims 9-16 and 17-20 do not identify any claim limitation supplied by expert testimony, but rather amount to a disagreement as to the prior art's disclosure of "semi-rigid" containers. Indeed, Patent Owner can only point to dependent claims 6- 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 23-24.) 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 after autoclaving and storage,” and Petitioner's expert's testimony is simply used to show a reasonable expectation of success. (Petition at 35-37 (autoclaving prior art), 37-39 (prior art disclosures of stability).)

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

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

Petitioner's Grounds 1-2 rely on prior art and arguments that have not been considered by the Office. Specifically, Ground 1 is based on the CMP Art in view of Terlevich and Perks, optionally in view of Ogawa, while Ground 2 adds Nevakar. (Petition at 4.) As Patent Owner concedes, none of this prior art, except for CMP-PCT, was before the Examiner during prosecution. (PO-Brief at 4-5.) 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 13, n.4.) Thus, Patent Owner's contention that 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 5.)

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 150-152; Petition at 5.)

Patent Owner spends 4 pages arguing the art of Terlevich, Perks, Ogawa and Nevakar are "cumulative," yet Patent Owner cites *nothing* in the prosecution history in support of its allegation. (PO-Brief at 6-9.) 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

⁴ The '291 patent incorrectly refers to Thomas as "U.S. Ser. No. 10/632,150." (Ex-1001 at 2:48-50.) The serial number for Thomas is 16/389,181, while its patent number is 10,632,150.

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. Patent Owner spends pages arguing why Terlevich fails to disclose a “flexible polymeric container” despite Terlevich's undisputed disclosure of a semi-rigid container, i.e., at least somewhat flexible container. (PO-Brief at 6-7.) Moreover, Patent Owner's own evidence proves that “semi-rigid” containers are “flexible:”



Figure 2 Open Infusion Container - Semi-rigid container with air filter.

(Ex-2008 at 2, Figure 2.) As shown, this semi-rigid container has deformed due to administration of its IV solution, i.e., it is a flexible container; otherwise it would have remained in its original undeformed state.

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 7-8; Ex-1002 at 152 ("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 5.)

The Challenged Claims require a ready-to-use solution (RTU) comprising 15 mmol/100 ml phosphorus, and the combination of the CMP Art, Terlevich, and Perks render the Challenged Claims obvious. (Petition at 15-27.) 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 5:40-51 (defining ready-to-use solutions); Petition at 27-28; 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, 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 17-18.) 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”).)

Patent Owner's arguments regarding Perks (PO-Brief at 8-9) are likewise without merit. Patent Owner argues Perks's disclosure of “diluted phosphate solutions” with 15 mmol/100 ml of phosphate is cumulative of Koneru. (PO-Brief at 8-9.) Not so. As Patent Owner admits, Perks expressly discloses a solution with the claimed 15 mmol/100 ml phosphate concentration. (*Id.*) Patent Owner does not identify any such disclosure in Koneru and instead argues that, hypothetically, if one were to take Koneru's disclosure of a 30 mM/ml phosphate concentrate and dilute it in a 200 mL infusion container “at a dilution ratio of 1/200,” this would yield the same result. Tellingly, Patent Owner does not cite to any portion of Koneru disclosing this hypothetical solution.⁵ (*See* PO-Brief at 9.) For at least these reasons, the art and arguments with respect to Grounds 1-2 are new.

⁵ Patent Owner's admission shows the claims are unpatentable over Koneru. Moreover, should the Board determine that Perks is cumulative of Koneru with respect to the phosphate concentration, then this would be a material error by the

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.) Petitioner's argument is simple: the CMP Art discloses concentrated sterile, isotonic solutions in rigid containers, Terlevich discloses ready-to-use solutions in another type of container (semi-rigid), and Perks discloses conventional solutions for treating hypophosphatemia included 15 mmol/100 ml of phosphate—it was obvious to prepare ready-to-use versions of the CMP Art's sterile, isotonic solutions having 15 mmol/100 ml phosphate as per Perks, and seal/store those solutions in a ready-to-use container, as per Terlevich. (Petition at 16-19.) Sterility and tonicity are unaffected in the combination.

In sum, the art and arguments presented in Grounds 1-2 of the Petition were not previously before the Office, and discretionary denial under §325(d) is unwarranted.

IV. CONCLUSION

Office during prosecution, further supporting why discretionary denial is not warranted. (*See* Ex-1002 at 152 (Examiner allowed the applicable because Koneru allegedly did not disclose the claimed phosphorus concentration).)

As shown herein, discretionary denial is unwarranted. The challenged patent is new (no settled expectations), a District Court trial date is unknown, and a stay is likely. Moreover, five of the *Fintiv* factors favor Petitioner while the remaining *Fintiv* factor is neutral. Finally, the art and arguments of Grounds 1-2 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)....”).) (<https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>).

Patent No. 11,813,291
IPR2025-00779

Petitioner's Opposition Brief

Respectfully submitted,
GREENBERG TRAURIG, LLP

Date: August 20, 2025

By: /s/ Heath J. Briggs
Heath J. Briggs (Reg. No. 54,919)
1144 15th St. Suite 3300
Denver, CO 80202
Telephone: 303-685-7418
Facsimile: 720-904-6118
BriggsH@gtlaw.com

Counsel for Petitioner

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,
GREENBERG TRAURIG, LLP

Date: August 20, 2025

By: /s/ Heath J. Briggs
Heath J. Briggs (Reg. No. 54,919)
1144 15th St. Suite 3300
Denver, CO 80202
Telephone: 303-685-7418
Facsimile: 720-904-6118
BriggsH@gtlaw.com

Counsel for Petitioner