

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Petitioner

v.

NIVAGEN PHARMACEUTICALS, INC.,
Patent Owner

Case IPR2025-00893

U.S. Patent No. 11,878,076

**PETITIONER'S RESPONSE TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

LIST OF EXHIBITS

Exhibit No.	Exhibit Description
1053	Memorandum Order, <i>Nivagen, Inc. v. Sun Pharm. Ind., Inc.</i> , No. 2:24-cv-0036 (E.D. Tex. Aug. 8, 2025), ECF 71
1054	Text Order, <i>Nivagen, Inc. v. Sun Pharm. Ind., Inc.</i> , No. 2:24-cv-0036 (E.D. Tex. Aug. 11, 2025)
1055	Orphan Drug Designation and Approvals – Sun, <i>FDA</i> (Oct. 2, 2019), https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=703819 (last accessed Aug. 22, 2025)
1056	Orphan Drug Designation and Approvals – Nivagen, <i>FDA</i> (Feb. 27, 2020), https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=725819 (last accessed Aug. 22, 2025)
1057	Defendant Sun’s Motion to Stay Deadlines and Motion for Protective Order Pending Transfer, <i>Nivagen, Inc. v. Sun Pharm. Ind., Inc.</i> , No. 2:24-cv-0036 (E.D. Tex. Aug. 15, 2025), ECF 73
1058	<i>Sun Pharma Launches SEZABY™ (phenobarbital sodium) in the U.S. for Treatment of Neonatal Seizures</i> , SUN PHARMA. (Jan. 25, 2023), https://sunpharma.com/wp-content/uploads/2023/01/Press-Release-Sun-Pharma-launch-of-SEZABY%E2%84%A2-in-the-US.pdf
1059	Nivagen’s Supplemental Responses to Sun’s Second Set of Interrogatories, <i>Nivagen, Inc. v. Sun Pharmaceutical Industries, Inc.</i> , No. 2:24-cv-36-RWS-RSP (E.D. Tex.) (served May 16, 2025)
1060	Han, et al., <i>What the Latest Case Data Reveals About Stays Pending IPR</i> , IPLAW360 (Mar. 7, 2022), https://www.law360.com/articles/1470979
1061	Letter from FDA to Sun Pharmaceutical Industries, Inc. re: NDA Approval of NDA 215910, DRUGS@FDA (Nov. 17, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215910Orig1s000ltr.pdf
1062	Amended Rule 16 Scheduling Order, <i>PNY Techs., Inc. v. Netac Tech. Co. Ltd.</i> , No. 16-000657 (D. Haw. Dec. 21, 2017), ECF 119

1063	Pretrial Scheduling Order, <i>PNY Techs., Inc. v. Netac Tech. Co. Ltd.</i> , No. 18-07932 (D.N.J. Feb. 21, 2019), ECF 209
1064	Scheduling and Trial Order for Jury Trial, <i>Eaton Veterinary Pharm., Inc. v. Wedgewood Vill. Pharm.</i> , No. 4:15-cv-00687 (W.D. Mo. Jan. 8, 2016), ECF 34
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1066	Declaration of Justin T. Oakland

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I. INTRODUCTION

Pursuant to the Director’s memorandum concerning “Interim Processes for PTAB Workload Management” (Mar. 26, 2025) (“Director Memo”), Petitioner Sun Pharmaceutical Industries, Inc. (“Sun”) submits this brief opposing Patent Owner Nivagen Pharmaceutical, Inc.’s (“Nivagen”) Request for Discretionary Denial.

Nivagen primarily argued that review by the Board would be “a wasteful and futile exercise” because “trial in the district court is less than seven months away.” Paper 7 at 1. The posture of the district court case has fundamentally changed, mooted the bulk of Nivagen’s argument.

Nivagen sued Sun in the Eastern District of Texas (“EDTX”), which lacked venue. Petition at 68–69. Sun promptly moved to dismiss or transfer the case to a proper venue. The EDTX finally granted Sun’s motion on August 8, 2025, cancelled the scheduled *Markman* and all other hearings, and ordered that the case be transferred to the District of New Jersey. Ex-1053 (Order granting transfer); Ex-1054 (Order cancelling *Markman* and discovery motion hearings). Per the five-plus year median time-to-trial statistic for the District of New Jersey, trial is now unlikely to occur until approximately 2029—long after a Final Written Decision in this IPR. Moreover, precedent shows that the District of New Jersey is likely to stay the case if this IPR is instituted, further enhancing efficiencies.

There are other compelling reasons that review of the U.S. Patent No. 11,878, 076 (the “’076 patent”) is a worthwhile use of the Board’s resources.

First, Nivagen has no settled expectations. The ’076 patent just issued in 2024. Moreover, Nivagen never commercialized the ’076 patent.

Second, the merits are strong, and review would allow the Patent Office to correct two material errors by the Office during examination.

One, the Examiner mistakenly focused on *liquid* phenobarbital sodium prior art and **overlooked *lyophilized* phenobarbital prior art**, such as the “PIF” reference that is the basis of the Petition’s Ground 1 challenge. Petition at 13. This was a material error because the claims recite *lyophilized* phenobarbital sodium, and the ’076 patent contended the alleged invention was based on the “surprising” discovery that *lyophilizing* phenobarbital sodium results in a formulation that is more stable and resistant to degradation than known non-lyophilized phenobarbital sodium compounds. Ex-1001 at 2:4–24; 2:53–67. But lyophilized phenobarbital sodium was already known in the prior art. It just was not examined during prosecution.

Two, the Examiner **applied the wrong priority date** to the claims. The claims of the ’076 patent issued from a continuation-*in-part* (“CIP”) application and claim new matter from that CIP application. However, the Examiner mistakenly applied the priority date of an earlier application, one that did not have

support for the '076 patent claims. Had the Examiner applied the correct priority date, the claims Nivagen obtained in the '076 patent would have been invalid in view of Nivagen's own prior published application, the "'608 Publication" that is the basis of the Petition's Grounds 2 and 3 challenges. Petition at 38, 65.

Third, compelling public health interests further support institution. Both Sun and Nivagen applied for orphan-drug designation and exclusivity through the FDA. However, it was Sun (and not Nivagen) that was ultimately successful. It was not until 2023, after Sun had won the race for orphan drug exclusivity, that Nivagen amended claims of its then-pending '076 patent to try to cover Sun's product. Permitting discretionary denial in this circumstance would undermine public health policy and frustrate the Orphan Drug Act's incentives. This is particularly true because Nivagen's claims in their amended form would not have been allowed to issue, had the Examiner either considered the *lyophilized* phenobarbital sodium prior art or applied the correct priority date.

Fourth, the Board is better equipped than the district court to evaluate the complex patent law issues raised by the Petition, such as written description and the correct priority date for the challenged claims.

Finally, the *Fintiv* factors overwhelmingly favor review. As noted above, the district court case will now be transferred to New Jersey, where no trial is scheduled, the case is likely to be stayed if IPR is instituted, and in any event,

based on time-to-trial statistics, no trial will happen until approximately 2029.

Moreover, the district court case is still in the early stages. The *Markman* hearing that was scheduled in the EDTX was just cancelled, and while fact discovery was underway when Sun's transfer motion was granted, Sun has not even answered yet.

For these reasons, and the reasons provided below, Sun respectfully requests that the Director deny Nivagen's Request for Discretionary Denial and refer the Petition to the merits panel.

II. BACKGROUND

Sun and Nivagen each sought and received orphan drug designation for phenobarbital sodium indicated for treatment of neonatal seizures. Sun did so in October 2019 (Ex-1055), and Nivagen in February 2020 (Ex-1056). Obtaining an orphan drug designation is a prerequisite to obtaining orphan drug exclusivity from the FDA. 21 U.S.C. § 360bb(a)(1) ("A request for designation of a drug shall be made before the submission of an application..."); *see generally id.* §§ 360bb–cc.

Nivagen also filed patent applications in 2019 and 2021¹ directed to lyophilized phenobarbital sodium products, but those applications were expressly

¹ Provisional Application No. 62/903,511 (the "511 Application," Ex-1003), filed September 20, 2019, and Application No. 17/025,881 (the "881 Application," Ex-

limited to *amorphous* phenobarbital sodium compositions that *excluded* organic solvents, purportedly to achieve unexpected stability and improved safety. *See, e.g.*, Ex-1003 at 7–8 (¶¶ [0007], [0009]); Ex-1004 at 195–96 (¶¶[0008], [0011]), 636, 643.

In February 2022, Sun filed a New Drug Application (“NDA”) for SEZABY[®], the proprietary name of the product for which Sun sought orphan drug designation for treatment of neonatal seizures. Ex-1061 at 1 (noting Sun’s NDA was received by the FDA on February 17, 2022). In contrast to Nivagen’s patent applications that were pending at the time, SEZABY[®] was a lyophilized phenobarbital composition that *contained* organic solvents.

By June 2022, Nivagen still had not filed any NDA of its own. *See* Ex-1059 at 7–8 (Nivagen not identifying any NDA when asked to identify whether it submitted an NDA). Instead, on June 30, 2022, Nivagen sought to expand the scope of its patent coverage by filing a continuation-in-part application including extensive new matter, No. 17/854,914 (the “’914 CIP Application”, Ex-1007). The ’914 CIP Application included 28 columns and 19 tables of new subject matter

1004), filed September 18, 2021. The ’881 Application later published as U.S. Publication No. US2021/0085608 (the “’608 Publication”, Ex-1005).

disclosing, for the first time, *non-amorphous* phenobarbital sodium compositions *containing* organic solvents. Ex-1050 at 53–70 (highlighting new subject matter).

On November 17, 2022, the FDA approved Sun’s SEZABY[®] product, granting Sun seven years of Orphan Drug Exclusivity for the indicated use of treating neonatal seizures. Ex-1061.

On January 24, 2023—only two months after Sun had obtained Orphan Drug Exclusivity—Nivagen filed U.S. Application No. 18/100,804 (the “’804 Application”, Ex-1002) as a continuation of the ’914 CIP application that would issue as the ’076 patent. Nivagen then amended the application claims to *remove* all explicit mention of organic solvents, in an effort to ensure the claims would *cover* products—like Sun’s SEZABY[®]—that *had* organic solvents, while, at the same time, removing the obvious evidence that it was broadening the claims to capture new matter in an effort to keep its earlier priority date. Ex-1002 at 285–87.

The ’076 patent issued on January 23, 2024, and Nivagen filed suit against Sun in the EDTX that same day. Ex-2001 at 1.

As noted above, however, venue in the EDTX was improper. Sun neither resides in the EDTX nor maintains a regular and established place of business there. In June 2024, Sun moved to dismiss or transfer the case to the District of New Jersey. Ex-2001 at 4. On August 8, 2025, more than a year after the motion

was filed, the EDTX Court agreed with Sun and ordered that the case be transferred to the District of New Jersey. Ex-1053.

Because the EDTX Court did not rule on Sun’s venue motion for over a year, fact discovery was underway and *Markman* and other hearings had been scheduled. However, when the EDTX Court granted Sun’s venue motion, it also cancelled all pending hearings, including *Markman*. Ex-1054. Because the case has not yet been formally transferred to the District of New Jersey, the Court there has not yet entered a schedule, no trial date has been set in New Jersey, and Sun has not yet filed an Answer to the Complaint. Even though the case now indisputably sits in a state of limbo as the courts transfer it from one district to another, Nivagen unusually sought to push discovery forward under the EDTX Court’s schedule and oversight. On August 15, 2025, Sun moved for a stay and protective order pending completion of the transfer. Ex-1057. The EDTX Court has not ruled on the motion and the case remains in abeyance pending transfer.

III. DISCRETIONARY DENIAL IS NOT WARRANTED

A. The Factors Set Forth in the Director Memo Favor Institution

The Director Memo indicates that the Director will consider whether to exercise discretion to deny *inter partes* review based on several factors, including: (1) “[s]ettled expectation of the parties, such as the length of time the claims have been in force”; (2) “[t]he strength of the unpatentability challenge”; (3) compelling

“public health” interests; and (4) “[a]ny other considerations bearing on the Director’s discretion”. Director Memo at 2–3.

Nivagen does not meaningfully address any of these factors. Each weighs decisively against discretionary denial and in favor of referral.

1. The ’076 Is Newly Issued and Nivagen Has No Settled Expectations

The ’076 patent issued on January 23, 2024, and Sun promptly filed this challenge just 15 months later. The Director has repeatedly recognized that “[e]arly challenges to patents favor robust, predictable patent rights and **weigh against discretionary denial.**” *Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, IPR2025-00153, Paper 11 at 3 (Director June 12, 2025) (declining discretionary denial where the patent issued 25 months before the petition) (emphasis added); *see also Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2–3 (Director June 26, 2025) (declining to discretionarily deny petitions because the challenged patents issued 5–6 years prior); *Shenzhen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.*, IPR2025-00438, Paper 10 at 2 (Director July 17, 2025) (referring a petition to the Board where the challenged patents had only been in force for less than five years). Because the ’076 patent is so new, there are no settled expectations and Sun’s prompt challenge favors referral to the PTAB merits panel.

Moreover, the fact that a patent has not been “‘commercialized, asserted, marked, licensed, or otherwise applied’ in Petitioner’s ‘particularized technology space’” weighs against discretionary denial. *See Shenzen Tuozhu*, IPR2025-00438, Paper 10 at 2 (quoting *Intel Corp. v. Proxense LLC*, IPR2025-00327, Paper 12 at 2–3 (Director June 26, 2025)). Like in the *Shenzen* case, Nivagen has not commercialized the ’076 patent. *See* Ex-1059 at 7–8. While Nivagen sought and received an orphan drug designation for phenobarbital sodium indicated for treatment of neonatal seizures in February 2020 (Ex-1056), Nivagen did not obtain the requisite FDA approval and ultimately never even filed an NDA for a lyophilized phenobarbital sodium drug product. *See* Ex-1059 at 7–8.

2. The Petition Raises Strong Unpatentability Challenges, and the Examiner Made Two Distinct Material Errors

The merits of the Petition are exceptionally strong, weighing heavily against discretionary denial. *See, e.g., TCL Elecs. Holdings Ltd. v. Maxell, Ltd.*, IPR2025-00120, Paper 9 at 8–9 (PTAB May, 2025) (“[T]he Petition presents a particularly strong challenge on the merits, counseling against discretionary denial.”) This is particularly true because here the Office made errors material to patentability during examination of the patent application. *See, e.g., W. Digit. Techs., Inc.*, IPR2025-00701, Paper 9 at 2 (Director Aug. 14, 2025) (finding material error by

the Office during patent examination to favor institution); *Skullcandy, Inc. v. Earin AB*, IPR2025-00690, Paper 9 at 2 (Director July 31, 2025) (same).

As the Petition explains, the Office made *two* material errors during examination: (1) the Examiner failed to substantively consider *lyophilized* phenobarbital sodium prior art; and (2) the Examiner also applied the wrong priority date to the claims. In this circumstance, substantive review of the Petition’s challenges to allow for correction of those errors is a worthwhile use of limited Board resources.

First, the claims are directed specifically to *lyophilized* phenobarbital sodium compositions. Ex-1001 at Claims 1–20. According to the specification, the alleged invention is based on the “surprising” discovery that *lyophilizing* phenobarbital sodium results in a formulation that is more stable and resistant to degradation than known liquid phenobarbital sodium compounds. Ex-1001 at 2:4–24; 2:53–67. But importantly, the Examiner did not examine prior art directed to *lyophilized* phenobarbital sodium compositions, focusing instead on *liquid* prior art formulations of phenobarbital sodium. Ex-1002 at 267–72.

With Ground 1, the Petition presents a compelling obviousness challenge based on the Nobelbar Pharmaceutical Interview Form (“PIF”, Ex-1009), a 2011 printed publication that specifically discloses an additive-free, storage-stable *lyophilized* (not liquid) phenobarbital sodium injectable product. Unlike the prior

art the Examiner considered², PIF discloses, expressly or impliedly, all elements of the challenged claims except for the specific dosage amounts. But as the Petition explains, the claimed dosage amounts (*e.g.*, 65, 100, 130, and 200 mg doses) were widely known and routinely used in clinical practice for decades prior to the '076 patent's priority date. *See* Ex-1009 (PIF); Ex-1012 (Parker); Ex-1013 (West-Ward). While Parker and West-Ward were disclosed in an IDS during prosecution, the Examiner did not consider Parker or West-Ward in combination with a reference (such as PIF) disclosing *lyophilized* phenobarbital sodium. *See* Ex-1002 at 262, 271.

The Director has explained that where a petitioner demonstrates that the Office “erred in a manner material to the patentability of the claims” by overlooking disclosure in the prior art of element(s) that the patentee relies on as

² Neither PIF (Ex-1009) nor any other reference describing Nobelbar was submitted during the prosecution of the '076 patent. *See generally* Ex-1002. Sun notes that other publications referencing Nobelbar were submitted by a third party (not by Nivagen) during earlier prosecution of the parent '598 patent. Ex-1004 at 827. However, Nivagen did not resubmit or cite these materials during the '076 prosecution, and there is no indication the Examiner substantively considered them or realized that they disclosed *lyophilized* phenobarbital sodium.

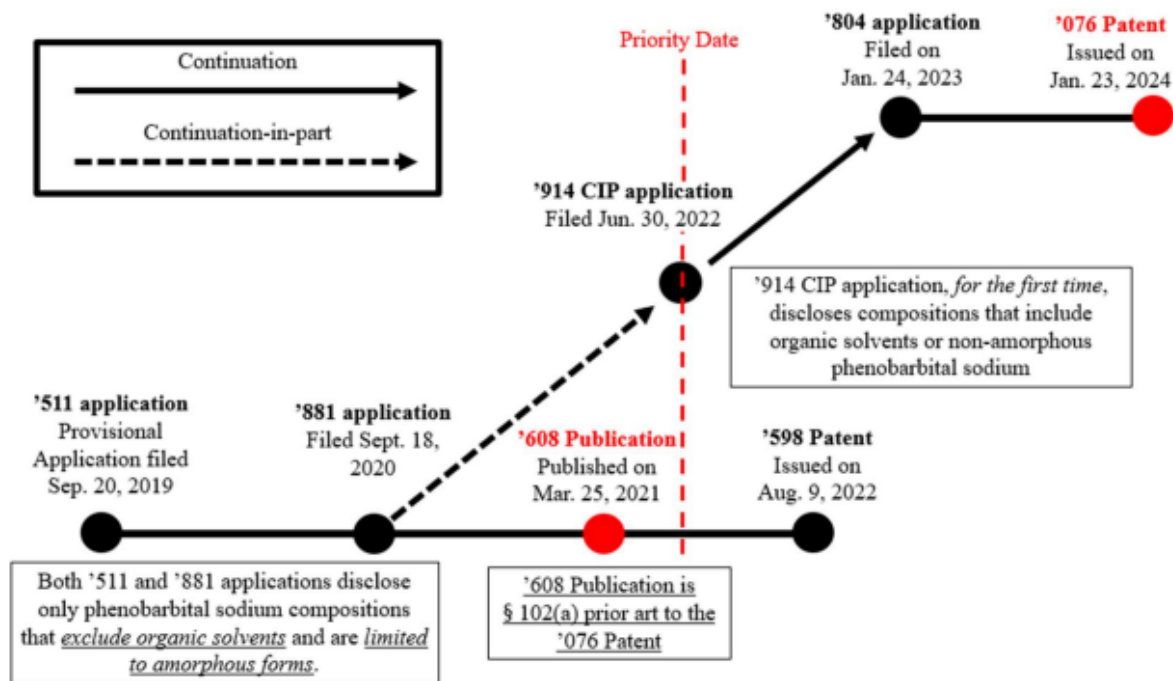
missing, review is warranted. *Tesla, Inc. v. Charge Fusion Techs., LLC*, IPR2025-00152, IPR2025-00153, Paper 11 at 2–3 (Director June 12, 2025) (“Petitioner persuasively argues that the patent examiner overlooked [the prior art reference’s disclosure of a purportedly missing element], thus demonstrating that the Office erred in a manner material to the patentability of the claims.” citing *Ecto World LLC v. Rai Strategic Holdings Inc.*, IPR2024-01280, Paper 13 at 5 (PTAB May 19, 2025) (precedential)); *see also CSPC Pharm. Grp. Ltd. v. Ipsen Biopharm Ltd.*, IPR2025-00505, Paper 11 at 3 (Director July 16, 2025) (denying discretionary denial request where petitioner provided evidence that the Office materially erred by “not considering or overlooking specific teachings” in disclosed prior art).

Nivagen’s final arguments to obtain allowance emphasized that Parker did not provide motivation for lyophilization (because it was already stable) and contained a number of co-solvents making it less pure than its compositions (below 98%). Ex-1002 at 289. Had the Examiner considered a reference specifically disclosing a storage-stable, additive-free *lyophilized* phenobarbital sodium, such as PIF, neither of those arguments would apply and the claims of the ’076 patent would not have issued. As the Petition explains, PIF’s disclosure of a *lyophilized* phenobarbital sodium composition that was additive free, in view of the teachings of Parker and West-Ward, renders the challenged claims invalid as obvious. Petition at 13–38.

The Office also materially erred by applying the wrong priority date to the claims of the '076 patent. As the Director has explained, this is a circumstance where discretionary denial is not appropriate. As the Director explained in *Padagis US LLC v. Neurelis, Inc.*, the Office's failure to determine and apply the correct priority date "raises concerns of material error such that review of the challenged patents is an appropriate use of Office resources." IPR2025-00464, Paper 12 at 3 (Director July 16, 2025).

Grounds 2 and 3 of the Petition explain that because the claims of the '076 patent only have support in the new matter added for the first time in the '914 CIP Application (Ex-1007) filed on June 30, 2022, they are not entitled to any earlier priority date. Petition at 38–67. The June 2022 '914 CIP Application was the first time Nivagen introduced subject matter encompassing *non-amorphous* phenobarbital compositions *containing* organic solvent. In total, Nivagen added 28 columns of new subject matter and provided claims with expanded scope encompassing this new disclosure (phenobarbital compositions that were *non-amorphous* and *contained* organic solvent) while eliminating the very features (*amorphous* compositions *free of* organic solvents) that had allegedly conferred benefits to the originally disclosed compositions. Ex-1050 at 53–70 (highlighting new subject matter); Ex-1002 at 285–87.

Despite these sweeping changes caused by the new matter, the Examiner never addressed the impact of the newly introduced subject matter and drastically broadened claim scope on the priority date for the claims of the '076 patent. Critically, the Examiner must have mistakenly assumed that those claims had priority back to the original applications filed in 2019 and 2020. This caused the Office to fail to consider the '608 Publication—which published after the original applications but more than a year *before* the '914 CIP application—as prior art. A schematic of the '076 patent family tree is provided below:



Petition at 10; Ex-1015 ¶ 21.

The Examiner applied the wrong priority date for the claims of the '076 patent. As the Petition shows, because the broadened claims of the '076 patent

captured subject matter not present in the 2019 and 2020 applications, the effective priority date is June 30, 2022. Petition at 49–53. When the claims are given the correct priority date, the '608 Publication—published more than a year before June 30, 2022—is prior art. Grounds 2 and 3 of the Petition show that had the Examiner applied the correct priority date, the claims of the '076 patent would have been invalid in view of the '608 publication and would not have issued. The Examiner's failure to apply the correct priority date is a material error by the Office.

The unpatentability challenge here is strong and seeks to redress two material errors made by the Office during prosecution of the '076 patent. This factor weighs heavily against discretionary denial.

3. There Is a Compelling Public Health Interest

The Director Memo also identifies “[c]ompelling economic, public health, or national security interests” as important considerations in the discretionary denial analysis. Director Memo at 2. Nivagen has not identified any such interest, and indeed Nivagen never obtained FDA approval to sell its own lyophilized phenobarbital sodium product.

By contrast, compelling public health considerations strongly favor referral of the Petition to the merits panel. Sun invested substantial resources in developing and successfully obtaining regulatory approval, including seven-years of Orphan Drug exclusivity, for its lyophilized phenobarbital sodium product, SEZABY®. *See*

Ex-1055; Ex-1058 (January 2023 press release); Ex-1061 (November 17, 2022 letter from FDA approving Sun’s NDA for SEZABY® “for the treatment of neonatal seizures in term and preterm infants”). Sun’s SEZABY® is the first and only FDA-approved phenobarbital formulation specifically indicated for the treatment of neonatal seizures—a rare and life-threatening condition. Ex-1058. Reflecting the seriousness and underserved nature of this patient population, the FDA granted Sun’s SEZABY® orphan drug designation request. Ex-1055. To encourage development of therapies for rare diseases, the FDA then provides the first sponsor obtaining FDA approval for an orphan indication seven years of marketing exclusivity. *See* 21 U.S.C. § 360cc.

Sun has invested substantial resources to develop SEZABY®, obtain FDA approval, and make this critical treatment available to newborns in need. Nivagen, by contrast, has no competing product on the market and has never filed an NDA for this drug. *See* Ex-1059 at 7–8. Rather, Nivagen ultimately did not complete the necessary regulatory steps to gain approval, and it was then Sun, not Nivagen, that was granted seven years market exclusivity under the FDA’s Orphan Drug Act. Only then did Nivagen turn to amending its patent portfolio, in an effort to obtain patent claims that it could use to try to block Sun from actually selling the treatment that Sun had earned FDA approval for and exclusivity under the Orphan Drug program. Nivagen’s attempt to manipulate its patent portfolio to impede

access to a life-saving therapy for infants runs counter to the public health interests the Director Memo seeks to protect. Accordingly, this factor weighs heavily against discretionary denial.

4. The Patent Office is the Better-Suited Forum

The Patent Trial and Appeal Board is a better-situated and more efficient forum than the district court to evaluate the complex issues presented in this case, including the critical question of whether the challenged claims are entitled to an earlier priority date.

In *Daiichi Sankyo Co., Ltd. v. Alethia Biotherapeutics, Inc.*, for example, the Board demonstrated that it is well-equipped to analyze and resolve complex issues involving continuation-in-part applications breaking the priority chain, such that a later filed patent is invalid in view of an earlier filed parent application. IPR2015-00291, Paper 75 (PTAB June 14, 2016).

The same is true here, where the Petition raises similar break-the-chain priority date issues. These are precisely the types of patent law-specific questions the Board is uniquely qualified to address with its technical expertise. Indeed, Petitions that present complex issues “tip the balance against discretionary denial.” *Cf. Tesla, Inc. v. United States*, IPR2025-00341, Paper 12 at 2 (Director June 13, 2025) (finding arguments regarding complex and diverse litigation to weigh against discretionary denial).

Moreover, here the Office materially erred by neglecting to assess whether newly added subject matter in the continuation-in-part application broke the priority chain. The Board, uniquely equipped to evaluate written description support, continuity, and invalidity, is the body best positioned to address and correct this error by the Office.

B. The *Fintiv* Factors Do Not Warrant Discretionary Denial

The *Fintiv* factors favor referring this IPR to the merits panel and denying the request for discretionary denial. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). The six factors are (1) whether a stay exists or is likely to be granted if IPR is instituted; (2) the “proximity of the court’s trial date to the Board’s . . . deadline for a final written decision;” (3) the “investment in the parallel proceeding by the court and parties;” (4) the “overlap between issues raised in the Petition and in the [litigation]”; (5) “whether the petitioner and defendant . . . are the same party;” and (6) “other circumstances that impact the Board’s exercise of discretion, including the merits.” *Id.* at 5–6.

Statistics show that a Final Written Decision will issue long before any trial in the District of New Jersey, and the District of New Jersey is likely to stay the case anyway in the event an IPR is instituted. Moreover, even in the highly unlikely event the case was not stayed, Sun has offered a *Sotera* stipulation that would significantly reduce any overlap in invalidity issues.

1. Factor 1 – The Parallel Litigation Will Likely Be Stayed If Trial Is Instituted

Factor 1 strongly favors institution. Should the Board institute trial, data reveals that the parallel litigation will almost certainly be stayed. The district court case was only recently ordered to be transferred to the District of New Jersey, where there is no trial date set, no scheduling order, and multiple outstanding discovery issues. If the Board grants institution, Sun will promptly move to stay the litigation pending resolution of the IPR.

The District of New Jersey routinely grants post-institution motions to stay—over 90% of the time (Ex-1060 at 2)—to conserve judicial resources, avoid redundant or conflicting opinions, and so that district courts can benefit from the PTAB’s view on validity. *See, e.g., Sage Prods., LLC v. Becton, Dickinson, and Co.*, No. 20-8000, 2022 WL 500569, at *1 (D.N.J. Feb. 18, 2022) (“Courts in this District ‘have noted a **generally liberal policy** toward granting stays pending patent reexamination by the PTO.’” (emphasis added) (quoting *Mondis Techs. Ltd. v. LG Elecs., Inc.*, No. 15-CV-4431, 2015 WL 7012747, at *5 (D.N.J. Nov. 12, 2015))); *Canfield Sci., Inc. v. Drugge*, No. 16-4636, 2018 WL 2973404 (D.N.J. June 13, 2018); *Cochlear Ltd. v. Oticon Med. AB*, No. 18-6684, 2019 WL 6309867 (D.N.J. Nov. 5, 2019); *Kirsch Rsch. & Dev., LLC v. GAF Materials, LLC*, No. 20-13683, 2021 WL 2434082 (D.N.J. June 15, 2021).

Moreover, any opposition to a motion to stay by Nivagen would fail on the merits. In determining whether to stay proceedings, courts consider: (1) whether the stay would prejudice the non-moving party; (2) “whether [the] stay would simplify the issues and the trial of the case; and (3) whether discovery is complete and a trial date has been set.” *Mondis Techs.*, 2015 WL 7012747, at *6 (quoting *Stryker Trauma S.A. v. Synthes*, No. 01-3879, 2008 WL 877848, at *1 (D.N.J. Mar. 28, 2008)). Each factor weighs decisively in favor of a stay.

First, Nivagen has no commercial product and is neither selling nor actively licensing goods related to the patent-at-issue; thus, it would suffer no prejudice from a stay. Second, a stay pending the Board’s review would unquestionably simplify the litigation, as every asserted claim in the district court is encompassed by the challenged claims in this Petition. Finally, because the case only recently was ordered to be transferred, the District of New Jersey has not yet set any trial date or provided any updated scheduling order.

Accordingly, if the Board grants institution, a stay of the parallel litigation is highly likely. This factor weighs overwhelmingly against discretionary denial.

2. Factor 2 – There Is No Trial Date Set

A Final Written Decision would issue long before any district court trial. Here a Final Written Decision would issue by mid-November 2026; based on the

District of New Jersey median time-to-trial statistics any district court trial would not begin until January 2029 (and possibly even later).

The parallel litigation was only recently ordered to be transferred to the District of New Jersey, and no trial date in New Jersey has been set. The New Jersey Court has not yet entered a new scheduling order, and Sun has not even answered or counterclaimed. According to 2025 statistics, the median time-to-trial in the District of New Jersey is 62.4 months (over five years).³ Therefore, even if one uses the January 2024 date that Nivagen improperly filed suit in the EDTX, the Board's Final Written Decision of mid-November 2026 would still issue *well* before any jury trial in New Jersey.

This case is just like the Director's recent decision in *Merck Sharp & Dohme LLC v. Halozyme, Inc.*, PGR2025-00006, Paper 29 (Director June 12, 2025). There, the Director denied a request for discretionary denial, explaining that "[t]he [New Jersey] district court has not yet scheduled a trial date, and the time-to-trial statistics [for the District of New Jersey] suggest trial would not begin until May 2030." *Id.* at 2–3.

³ <https://www.uscourts.gov/statistics-reports/analysis-reports/federal-court-management-statistics>.

The absence of a trial date in New Jersey, combined with a historic five-year time-to-trial for the District of New Jersey, weighs heavily against discretionary denial.⁴

⁴ Nivagen informed Sun that it believes the EDTX schedule should still control the litigation. Sun is aware of no case transferred to New Jersey where the court maintained the same schedule. More typically, the case schedule is materially extended. For example, in *PNY Techs., Inc. v. Netac Tech. Co. Ltd.*, 18-CV-07932 (D.N.J.), the court extended fact discovery by 16 months. *Compare* Ex-1062 with Ex-1063. Similarly, in *Eaton Veterinary Pharmacy, Inc. v. Wedgewood Vill. Pharmacy, Inc.*, 16-CV-02086 (D.N.J.), the court extended fact discovery by 7 months. *Compare* Ex-1064 with Ex-1065. Even more important, although both cases had trial dates before they were transferred, the District of New Jersey *did not set a trial date* in either post transfer, which will likely to occur here too. Nivagen does not sell a competing product negating any claim of urgency to cause the District of New Jersey to disrupt its already-booked schedule to fit in a new case—particularly a case where the plaintiff filed in the wrong venue. Any suggestion by Nivagen that the District of New Jersey will maintain the schedule imposed by the EDTX Court—or anything close—is contradicted by real world practice.

3. Factor 3 – The Parties Have Not Substantially Invested In the Parallel Litigation

Following the order granting transfer to the District of New Jersey, the case remains at an early stage. The *Markman* hearing that was scheduled in the EDTX was cancelled. Ex-1054. Sun has not yet filed an answer. Fact discovery remains ongoing, with discovery disputes outstanding and multiple fact depositions yet to be taken. Ex-1053; Ex-1054; Ex-1057. Expert discovery has not yet begun, no expert reports have been exchanged, and there has been no claim construction order or *Markman* hearing. Neither the Court (the EDTX, where venue was improper, or the District of New Jersey, where the case will be transferred), nor the parties, have made significant investments in the merits of the case. Indeed, the case was just (finally) transferred to the proper venue in New Jersey. With most substantive work ahead, denying institution would not be warranted. This factor weighs heavily against discretionary denial.

4. Factor 4 – There Will Be Limited, If Any Overlap in the Proceedings

Fintiv Factor 4 considers the extent to which there is “overlap between issues raised in the petition and in the parallel proceeding.” Here, there is likely to be limited, if any, overlap, for two separate reasons.

One, as explained above, this case has now been transferred to the District of New Jersey, and if this IPR is instituted the district court case is likely to be stayed.

And in the event the district court case is stayed, there will be little overlap in proceedings, because either the Final Written Decision will invalidate the challenged claims, or if not, Sun will then be estopped from pursuing any invalidity ground that it raised or reasonably could have raised during the IPR.

Two, even if the district court case somehow was not stayed, Sun has unequivocally agreed to a *Sotera* stipulation should the Board institute this proceeding. Ex-2019.⁵ This means Sun has promised that, in the event this IPR is instituted, Sun will not pursue any invalidity ground that Sun raised or reasonably could have raised during this IPR.

Nivagen spends much time pointing out that references and combinations from the Petition (for example, “PIF,” “Parker,” and “West-Ward”) also appear in the Amended Invalidity Contentions that Sun served in the district court litigation on May 8, 2025. *See, e.g.*, Paper 7 at 18–28. This is a red herring. As Sun pointed out above, Sun does not intend to (and has expressly agreed not to) pursue parallel invalidity arguments in the district court case based on grounds that Sun raised or reasonably could have raised during the IPR. If the IPR is instituted, either (i) the

⁵ Nivagen contends that Sun somehow “has not entered” a *Sotera* stipulation. Paper 7 at 28–29. But as Nivagen acknowledges, Sun has already agreed to a *Sotera* stipulation, in the event the IPR is instituted. Ex-2019 at 1.

district court will be stayed pending the IPR, in which case Sun would be estopped from pursuing such grounds in the district court once a Final Written Decision in the IPR issues, or (ii) in the unlikely event the district court case were not stayed, then Sun has agreed to the same scope of estoppel via a *Sotera* stipulation. The reason that Sun identified the IPR grounds and references in its district court Amended Invalidity Contentions is because there was a disclosure deadline in the district court case for invalidity contentions, and there has not yet been an institution decision. Ex-2002 at 4. Sun very reasonably sought to preserve the IPR invalidity grounds for the district court case *in the event the IPR was not instituted*.

Sun is also relying on the Nobelbar commercialized product itself in the district court litigation, including nonpublic documents disclosing that product. However, grounds based on the commercialized Nobelbar product itself, including those that include non-public documents as supporting evidence, are not grounds that can be brought in an IPR. *Ingenico Inc. v. IOENGINE, LLC*, 136 F.4th 1354, 1366–67 (Fed. Cir. 2025). Sun recognizes and acknowledges Director guidance noting that where a petitioner is “relying on corresponding system art in a co-

pending proceeding” a *Sotera* stipulation may carry less weight.⁶ However, this alone does not outweigh other considerations.

Here, the *Sotera* stipulation does significantly increase the efficiency. It ensures that Sun will not pursue the parallel patent/printed publication grounds currently in its district court Amended Invalidity Contentions, in the event this IPR is instituted. Further, there were at least two material errors by the Examiner during examination of the '076 patent here: the failure to consider shelf-stable *lyophilized* phenobarbital sodium prior art, and the failure to apply the correct priority date to the examined claims. It is a worthwhile use of Board resources to institute this IPR and correct those errors, before Sun is forced to defend itself in a district court proceeding concerning enforcement of those claims.

5. Factor 5 – The Petitioner is the Defendant in the Parallel Litigation

As Nivagen notes, Sun is the Defendant in the parallel district court litigation. This is true of most IPR petitioners, and as the Board has noted, this factor adds “little if anything to the discretionary denial analysis unless the petitioner is not named as a defendant . . . in parallel district court patent

⁶ <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>, at Section I.D.

litigation.” *Aylo Freesites Ltd. v. WellcomeMat, LLC*, IPR2024-00710, Paper 13 at 17–18 (PTAB Sept. 5, 2024). This factor is neutral.

**6. Factor 6—Any Other Relevant Circumstances Including
Strength of the Merits—Weighs Against Discretionary Denial**

This factor also strongly weighs against discretionary denial.

As explained above, here the merits are strong. Sun is seeking *inter partes* review because the Office did not consider a shelf-stable *lyophilized* phenobarbital sodium prior art reference during prosecution, and also because the Office applied the wrong priority date to the claims during prosecution. Instituting review will allow the Office to redress these errors, by reviewing the patentability of the claims in view of a shelf-stable lyophilized phenobarbital sodium reference (Ground 1, based on “PIF”), and by considering the claims with the correct priority date applied (Grounds 2 and 3, with the ’608 Publication properly considered prior art).

Moreover, as explained in Sections II.A.1 and II.A.3, the ’076 patent just issued in 2024, Sun promptly challenged it, and there is also a strong public interest in reviewing a patent that Nivagen is trying to use to block Sun from exercising the Orphan Drug exclusivity period that Sun was granted from the FDA. Furthermore, referral to the merits panel here is consistent with the significant public interest against “leaving bad patents enforceable.” *Thryv, Inc. v. Click-To-Call Techs., LP*, 590 U.S. 45, 55 (2020). Finally, this Petition is the sole challenge

to the '076 patent before the Board—a “crucial fact” favoring institution. *Google LLC v. Uniloc 2017 LLC*, IPR2020-00115, Paper 10 at 6 (PTAB May 12, 2020).

Nivagen argues that discretionary denial is warranted because Sun is advancing “contradictory” claim constructions between this proceeding and the district court litigation and that would make the Board’s decision “merely advisory” or “redundant.” Paper 7 at 5, 31–32. That is not correct, and Nivagen’s arguments do not support discretionary denial.

First, the Board’s Final Written Decision will not be “redundant” or merely “advisory.” And there will be no loss in efficiency, in the event the IPR is instituted. Nivagen does not dispute in the IPR that the term “composition” should have its plain and ordinary meaning. Paper 8 at 15 (Nivagen POPR, stating “[n]onetheless, both in the district court and for the purposes of this proceeding, Nivagen does not believe any claim terms require construction.”). If the Board agrees in the Final Written Decision that the claims are invalid and should not have issued applying the agreed-to plain and ordinary meaning of the term “composition,” then there is no need for any further work in the district court action. The claims of the '076 patent will be invalid.

If, on the other hand, the Board finds in the Final Written Decision that the claims are patentable, again applying the agreed-to plain and ordinary meaning of “composition,” then there will have to be a district court trial anyway on

infringement. By reserving the right to make an alternative disclaimer argument in the district court (i.e., that the claims should be given a definition that is narrower than plain and ordinary meaning), Sun is not creating any undue inefficiencies.

Second, the Board has expressly recognized that the “rules do not prohibit a petitioner from taking inconsistent claim construction positions before the Board and a district court.” *E.g., Cambridge Mobile Telematics, Inc. v. Sfara*, IPR2024-00966, Paper 12 at 8 (PTAB Dec. 13, 2024). Here, Sun is merely exercising its right to argue in the alternative and has expressly reserved the right to address claim construction issues in the parallel litigation, including its argument that Nivagen disclaimed compositions containing organic solvents. Petition at 13.

IV. SUN RESPECTFULLY SUBMITS THAT THE INTERIM CHANGES TO THE INSTITUTION DECISION PROCEDURE DO NOT COMPLY WITH 35 U.S.C. § 316 AND THE APA

Sun respectfully submits that the standards articulated in the June 21, 2022 Director Vidal Memo should govern this Petition until such time as the USPTO promulgates regulations in accordance with 35 U.S.C. § 316 and the Administrative Procedure Act (“APA”). Under those standards, the Petition also should not be discretionarily denied, at least because Petitioner here has offered a *Sotera* stipulation.

On March 26, 2025, the USPTO issued a Process Memorandum introducing a new “interim process” that bifurcated institution between discretionary

considerations and statutory merits. The USPTO also issued additional guidance on the discretionary considerations process via the Interim Director Discretionary Process webpage.⁷ This guidance marked a significant change in institution procedures without notice-and-comment rulemaking, despite the USPTO's prior representation that such future changes would be implemented through formal rulemaking. *See* 88 Fed. Reg. 24503 (Apr. 21, 2023).

Sun respectfully submits that the interim guidance regarding the new bifurcated institution decision approach does not comply with 35 U.S.C. § 316(a), which requires the Director to “prescribe regulations” setting forth the standards for institution. The interim guidance was not implemented via the formal rulemaking process and did not provide a reasoned explanation for departing from prior standards. *See FDA v. Wages & White Lion Invs.*, 145 S. Ct. 898, 918 (2025) (explaining that when an agency changes policies, it must “offer ‘good reasons for the new policy’”) (quoting *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); *see also Fox Television Stations*, 556 U.S. at 515 (holding that an agency must show “that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates”). Sun therefore respectfully

⁷ <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

requests that the Board apply the June 2022 Vidal Memo standards in assessing discretionary denial, until such time as any new procedures are implemented through notice-and-comment rulemaking.

V. CONCLUSION

For the foregoing reasons, the discretionary denial considerations overwhelmingly support institution. Sun respectfully requests that the Director deny Nivagen's Request for Discretionary Denial and refer the Petition to the panel so that the Petition can be considered on its merits.

Date: August 25, 2025

Respectfully submitted,

/J. Derek Vandenburg/

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CERTIFICATE OF WORD COUNT

Under 37 C.F.R. § 42.24(d), Sun certifies that this Response to Nivagen's Request for Discretionary Denial has a word count of 6,750, excluding the portions exempted by 37 C.F.R. § 42.24(a), as calculated by the built-in word-count function in the Microsoft Word software used to prepare this document.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on August 25, 2025, a complete copy of the foregoing Response to the Request for Discretionary Denial, Exhibit List, and all supporting exhibits were served electronically on Nivagen's counsel of record at the below. Nivagen's counsel agreed to dispense with service of paper copies.

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