

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 REQUEST FOR DIRECTOR REVIEW OF DECISION
DENYING INSTITUTION OF *INTER PARTES* REVIEW**

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.75 and the Interim Director Discretionary Process guidance, Petitioner Sun Pharmaceutical Industries, Inc. (“Petitioner”) respectfully requests that the Director vacate the Decision Denying Institution of *Inter Partes* Review (Paper 18, September 19, 2025) (“Decision” or “discretionary Decision”) and either institute review or refer to the Board for further proceedings.

Director Review is warranted here. The Decision acknowledged that multiple discretionary factors favored referral. Institution was nevertheless discretionarily denied, and the *only* factor identified as favoring denial was Petitioner’s alleged failure to sufficiently explain a claim construction issue. However, the Office’s guidance expressly identifies “claim construction issues” as examples of “*non*-discretionary considerations.” And while the Decision faulted Petitioner for not adequately explaining why it was arguing disclaimer only in the district court case, the Office guidance and prior Board and Federal Circuit decisions had all consistently explained that there was no need to resolve a claim construction issue if there is no dispute about claim construction in the IPR (outside of means-plus-function claims). That is the situation here. Petitioner followed Office guidance in stating in the Petition that no express construction was required to resolve the IPR, and Patent Owner agreed. Petitioner had no fair notice of any change in the Office’s approach.

Even if a claim construction issue were now a basis for discretionary denial, Petitioner has good reasons for advancing its disclaimer argument only in the district court proceeding—and the Director should consider those. Patent Owner vehemently opposes Petitioner’s district court disclaimer argument and, at the same time, Patent Owner contends its wrongly-issued patent should be afforded an earlier priority date that is only proper if Petitioner’s disclaimer position is adopted. Patent Owner should not be permitted to evade *inter partes* review by merely pointing out that Petitioner is making a disclaimer argument in a different forum, while at the same time maintaining (to the public, the Patent Office, and Petitioner) that it *is* in fact entitled to the full scope of the ordinary meaning of the claimed “composition,” which was broadened to include new matter as explained in Grounds 2 and 3 of the Petition. This is particularly true where—as here—Petitioner was unable to get resolution of the disclaimer issue in the district court case prior to the one-year bar for filing an IPR.

Finally, there is another independent reason Director review is warranted: the discretionary Decision was issued *after* the Director had been confirmed, but by a person other than the Director and before the Director had indicated who was to exercise the Director’s discretionary authority.

For all of these reasons, Petitioner respectfully requests that the Director review and vacate the Decision discretionarily denying the Petition.

II. FACTUAL BACKGROUND

This case presents a unique situation that makes review of the issued '076 patent a particularly worthwhile use of Patent Office resources. Petitioner and Patent Owner each sought and received “orphan drug” designation for a lyophilized phenobarbital sodium product indicated for treatment of neonatal seizures, under FDA procedures intended to incentivize companies to develop orphan drug treatments. However, it was then Petitioner (not Patent Owner) that invested in filing a New Drug Application (“NDA”) and in obtaining the necessary supportive information and data to seek approval. And it was Petitioner (not Patent Owner) that obtained FDA approval (and the accompanying orphan drug exclusivity period) for its orphan drug SEZABY®.

Patent Owner, having failed in its effort to develop its own lyophilized phenobarbital sodium orphan drug, then turned to using patents to try to block Petitioner’s SEZABY®. In an effort to ensnare SEZABY®, Patent Owner took an existing continuation application, added new matter, and broadened the claims. Patent Owner had to do this because its application at the time was limited to *amorphous* phenobarbital sodium compositions that *excluded* organic solvents, while Petitioner’s SEZABY® *included* organic solvents. To convince the Patent Office to issue the broadened claims (which the Patent Office did in 2024), Patent Owner relied on arguments regarding 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. *E.g.*, Ex-1001 at 2:4–24 and 2:53–67. What the Examiner did not realize, however, is that *lyophilized* phenobarbital sodium was already known in the prior art.

Petitioner therefore filed this Petition to challenge the wrongly-issued claims. The Petition relies on two grounds: (1) a ground based on a *lyophilized* phenobarbital sodium prior art reference, and (2) an alternative ground based on the prior publication of Patent Owner’s patent application, which became prior art once Patent Owner obtained the broadened claims that were no longer supported by the priority application.

In its Petition, Petitioner followed the guidance in the Consolidated Trial Practice Guide (“CTPG”) regarding claim construction. The CTPG states that “a petitioner may include a statement that the claim terms require no express construction” and “[t]he patent owner may then respond to these positions and/or propose additional terms for construction.” CTPG at 44. The Petition did precisely that, stating that “Petitioner does not believe any claim terms require specific construction for the purpose of deciding the Grounds 1–3 challenges set forth in this Petition.” Petition at 13.

The Patent Owner then had an opportunity to respond, as outlined in the CTPG. But in its response, Patent Owner *agreed* no term required construction:

“Nivagen does not believe any claim terms require construction.” Paper 8 at 14.

III. THE DISCRETIONARY DENIAL DECISION

In the discretionary briefing, Petitioner explained that the discretionary factors strongly favored referral. These include: (i) that there are no settled expectations because the '076 patent just issued in 2024, (ii) that there were two material errors made by the Office during original examination, (iii) that there are public health interests in incentivizing orphan drug development, and (iv) that the district court case is still in its early stages with no trial date scheduled. Paper 14 at 7-17, 20-23.

The Petition was discretionarily denied on September 19, 2025. Paper 18. The discretionary denial Decision *agreed* multiple factors weighed against denial, noting that there was not yet a district court trial date and that the patent had not been in force for a significant period of time. *Id.* at 2. The Decision identified only one factor as favoring discretionary denial: “Petitioner has taken different claim construction positions in this proceeding and the parallel district court proceeding” as to the term “composition,” and that allegedly “Petitioner does not sufficiently explain why it advanced a narrow construction in district court and advances a broader construction in its Petition.” *Id.* at 2-3.

IV. ARGUMENT

A. The Director Should Vacate the Discretionary Denial Decision

The only factor identified as favoring discretionary denial was an alleged failure by Petitioner to “sufficiently explain” in the *discretionary* briefing its claim construction position for the term “composition” in this IPR. But the Office’s guidance for the discretionary denial procedure expressly identifies “claim construction issues” as examples of a “*non*-discretionary considerations.” Moreover, the Petition followed existing Office guidance in its approach to claim construction, which guidance stated that for non-means-plus-function terms a Petitioner could state that no express construction was required. The Decision discretionarily denying the Petition based on an alleged failure to sufficiently explain a *non*-discretionary issue, where Petitioner also followed existing Office guidance regarding that issue, was an abuse of discretion and should be vacated.

1. Existing Office Guidance Identifies Claim Construction Issues as “Non-Discretionary Considerations”

The Office has provided parties with guidance entitled “Interim Director Discretionary Process” (“Process Guide”), available at <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>. The Process Guide “serves as a guide to parties on when and how to file discretionary briefing, and the process by which the [Director] will render decisions on

discretion.” *Id.* At Section I.F, in a section titled “Merits, non-discretionary considerations, and motions,” the Process Guide states that “***claim construction issues***” are “***non-discretionary considerations***”:

[N]on-discretionary considerations include those relevant to, for example, 35 U.S.C. §§ 311, 312, 315(a), (b), and (e), 322, and 325(a) and (e). *Such considerations also may include*, for example: (1) ***claim construction issues*** (*see, e.g., Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 (PTAB Dec. 13, 2024) (informative))

Id. (emphasis added).

Notwithstanding the Process Guide, the discretionary Decision denied institution based on an alleged failure to sufficiently address a claim construction issue, citing *Cambridge Mobile*. Paper 18, 2-3. The Decision acknowledged that other factors weighed against denial; the claim construction issue was the *only* one identified as weighing in favor. *Id.* 3. This was an abuse of discretion. It is inequitable and also a due process violation to provide the guidance in the Process Guide, accept briefing directed to *discretionary* considerations, and then issue a *discretionary* decision where the only stated reason for the decision concerns a *non-discretionary* consideration.

Moreover, the *Cambridge Mobile* case is directed to the sufficiency of the *Petition* for *means-plus-function* terms. *Cambridge Mobile Telematics, Inc. v.*

Sfara, IPR2024-00952, Paper 12 at 8 (P.T.A.B. Dec. 13, 2024) (informative)

(“Under these facts we determine that 37 C.F.R. § 42.104(b)(3) mandates that the *Petition* ‘identify the specific portions of the specification that describe the structure...’”) (emphasis added). It was an abuse of discretion to support a *discretionary* decision by citing a case holding directed to the sufficiency of a *Petition* for a means-plus-function term, particularly where—as here—the term is not means-plus-function.¹

2. Petitioner Should Not Be Penalized for Having Followed Existing Office Guidance and Case Law

In stating in the *Petition* that the term “composition” required no express construction for the purpose of resolving the IPR, Petitioner also followed existing

¹ Petitioner’s discretionary brief responded to the portion of Patent Owner’s *Fintiv* argument regarding purported inconsistent claim construction positions by explaining why there would not be inefficiencies. Paper 14 at 27-29. Petitioner’s brief did not specifically explain *why* it was seeking to prove disclaimer only in the district court, because (i) Office guidance identified claim construction issues as a “non-discretionary considerations,” and (ii) in the IPR the parties *did not dispute* plain and ordinary meaning should apply, and Office guidance, Board and Federal Circuit decisions all indicated in such circumstance no construction was required.

Office guidance. The CTPG tells parties that “*a petitioner may include a statement that the claim terms require no express construction.*” CTPG at 44. Then, the patent owner can respond and propose terms for construction, if it thinks that construction is required for the IPR. *Id.* Consistent with this guidance, the Board’s prior decisions have repeatedly noted a Petitioner need not raise all claim construction arguments from the district court in the IPR Petition, particularly where—as here—there is *no dispute* about the construction to apply in the IPR and *no construction* has been issued by the district court. *E.g., Dish Network LLC et al. v. Digit. Broad. Sols., L.L.C.*, IPR2023-00976, Paper 8 at 7-9 (P.T.A.B. Dec. 11, 2023); *Samsung Elecs. Co. v. Smart Mobile Techs. LLC*, IPR2022-01248, Paper 13 at 58 (P.T.A.B. Jan. 24, 2023); *10x Genomics, Inc. v. Bio-Rad Lab’ys, Inc.*, IPR2020-00086, Paper 8 at 18 (P.T.A.B. Apr. 27, 2020); *see also Oneplus Tech. (Shenzen) Co. v. Pantech Corp.*, IPR2025-00762, Paper 10 at 9-10 (P.T.A.B. Oct. 15, 2025) (same). And the Federal Circuit has likewise recognized that in an IPR, “only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.” *E.g., Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Here, the Petition followed Office guidance, stating in the Petition that no claim terms required specific construction for the purpose of the IPR. Patent Owner then *agreed* no construction was needed.

It is also logical that the Office guidance has blessed this approach and that PTAB cases follow it. In a case such as this one, where (i) the Patent Owner is contending there was no disclaimer, (ii) the parties to the IPR *agree* that no construction is required to resolve the IPR, and (iii) there has not been any resolution of the disclaimer issue in the district court case within the one-year statutory bar period despite the Petitioner expeditiously seeking resolution there, the Petitioner should not be forced to address and try to prove disclaimer in the IPR anyway. Such an approach would force parties to seek advisory claim construction opinions from the Board about claim construction issues they are not actually disputing before the Board.

The discretionary denial Decision also cites statements from the Federal Register that explain how the Board will conduct claim construction, and in doing so note that using the same claim construction standard as district courts improves “uniformity and predictability” and “increase[s] judicial efficiency.” *See* Paper 18 at 3 (citing 83 Fed. Reg. 51342). But the concerns of “uniformity,” “predictability,” and “efficiency” underlying the use of the same *Phillips* claim construction standard in each forum are not implicated here. Petitioner is *not* seeking to have the term “composition” construed here. There is no dispute about what the term “composition” means (without disclaimer), and both parties to this IPR (Patent Owner and Petitioner) agree that for this IPR it does not need to be construed.

Petitioner has merely chosen not to try to carry its burden to prove *disclaimer* in this IPR, because that is an issue that primarily goes to infringement.

Moreover, the Rule implemented with the Federal Register commentary cited in the Decision states that in construing claims the Board will consider “[a]ny prior claim construction *determination*.” 37 C.F.R. § 42.100(b) (emphasis added). Here, there was no prior “determination” for the Board to consider, nor was there even an imminent possibility of such a determination being issued. At the time the Petition was filed, the parties had not yet even exchanged proposed constructions in the district court case. And when Petitioner responded to Patent Owner’s discretionary denial brief, the district court claim construction hearing had been cancelled and the case transferred to a new district. Ex-1054; Ex-1053.

Finally, the discretionary denial Decision was also an abuse of discretion for another reason. An IPR petitioner must pay a non-refundable filing fee of \$23,750. It is an unjustified taking of that filing fee to discretionarily deny a petition on a basis that Office guidance expressly identifies as a “non-discretionary consideration,” and also to penalize Petitioner for following the Offices own guidance regarding claim construction in a Petition. Had Petitioner had notice that such claim construction issues would be considered and applied instead as discretionary considerations, and also to non-means-plus-function claim terms, it could have further explained its rationale.

B. The Director Should Find the Discretionary Factors Weigh Against Denial and Consider Institution on the Merits

If the Director considers claim construction issues to be part of the discretionary considerations, notwithstanding the Office guidance indicating they are not, then the Director should also consider Petitioner's reasons for why it is only pursuing the disclaimer argument for the term "composition" in the district court case. And the reasons are good ones.

This IPR and the parallel district court litigation involve a situation in which Patent Owner must walk an impossible tightrope—either: (1) Patent Owner disclaimed compositions containing organic solvents and, therefore, Petitioner does not infringe; or (2) Patent Owner did not disclaim compositions containing organic solvents, and its patent is anticipated by its own priority application. In the first scenario, where Patent Owner disclaimed compositions containing organic solvents, the relevant issue is non-infringement—an issue that this tribunal cannot resolve. In the second scenario, by contrast, in which Patent Owner is found not to have disclaimed compositions containing organic solvents, the primary relevant issues are priority and anticipation by Patent Owner's own priority application—issues that this tribunal *is* uniquely positioned to address. Thus, for purposes of this IPR, Petitioner chose to agree to proceed under the second scenario—advanced by Patent Owner—that there was no disclaimer of the term "composition." Petitioner

is not being inconsistent with respect to its positions before the Board and the district court; it is merely preserving its rights under both scenarios, given that it cannot know at this point whether disclaimer will be applied by the district court.

Discretionary denial in this circumstance unfairly benefits Patent Owner: Patent Owner evades Board scrutiny of its wrongfully granted patent but maintains the ability to turn around and argue infringement in the district court based on the very same no-disclaimer position that **both** Petitioner and Patent Owner have agreed applies in this proceeding. This result is inequitable when Patent Owner itself is holding out—to Petitioner, to this tribunal, to the district court, and to the world—that Patent Owner is entitled to the full scope (no disclaimer) of the term “composition.” That Petitioner has agreed to apply the full scope of the term for purposes of this IPR is not inconsistent, but instead is Petitioner’s chance for review of the patent by the Board based on the presumptive scope of the claims that the Patent Owner is contending it is entitled.

The rationale relied upon by the Director in the Decision confirms the inequity in this situation. Specifically, the Decision states that “*if a party advances a narrow construction in the district court and the district court declines to adopt the narrow construction, the party would have sufficient reason for advancing the broader court-adopted construction in a proceeding before the Board.*” Decision at 3. But given the one-year bar for filing an IPR following service of a complaint, it

would be highly unusual for the district court case to have proceeded to the point that the parties know whether or not the district court will adopt the narrower construction in time for a party to then file a timely IPR petition. And indeed, that is the case here. Despite Petitioner expeditiously seeking to transfer the district court case to the proper venue and also fully briefing claim construction while its transfer motion was pending, there still has been no decision in the district court. Thus, in situations like this, discretionary denial allows the Patent Owner to evade review by the Board due solely to the fact that Petitioner has not yet been able to secure a determination from the district court regarding whether Petitioner has proven disclaimer. Such a result is neither efficient nor just.

The result in this particular circumstance is even less fair because, as Patent Owner has emphasized in the district court action, the bar for proving disclaimer is high—the party seeking to invoke disclaimer “bears the burden of proving the existence of a ‘clear and unmistakable’ disclaimer.” Opening Claim Construction Brief at 10, *Nivagen, Inc. v. Sun Pharms. Indus., Inc.*, No. 2:24-cv-00036 (June 9, 2025), Dkt. No. 58 (quoting *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016)). Thus, if the Decision stands, petitioners in this situation will be faced with an unfair dilemma: either forego the disclaimer argument entirely in order to have a chance to pursue review by the Board *or* forego the ability to seek Board review.

C. The Decision Was Issued By Someone Other than the Director, After the Director Had Already Been Confirmed

Director Review is merited for an additional reason: the Decision was issued after the Director had been confirmed, but by a person other than the Director and before the Director had indicated who was to exercise the discretionary authority.

The Office has stated that the Director should decide discretionary issues. *E.g.*, Process Memorandum (March 26, 2025) (“the Director” will decide). And as of today, the Director will decide both discretionary and merits issues.

Memorandum, Director Institution of AIA Trial Proceedings (October 17, 2025).

The discretionary Decision this case was issued on September 19, by the individual who had been serving as the Acting Director. However, this was in the window after the Director had been confirmed (on September 18, 2025) but before the Director delegated discretionary authority to the Deputy Director (on September 26, 2025). Petitioner respectfully submits that at least during that window, either the discretionary decision should not have issued or it should have been issued by the Director himself.

V. CONCLUSION

For the foregoing reasons, the Decision discretionarily denying institution should be reviewed and vacated, and the Director should either institute review or refer the Petition to the Board for further proceedings.

Date: October 20, 2025

Respectfully submitted,

/s/ J. Derek Vandenburg

J. Derek Vandenburg

Registration No. 32,179

CARLSON, CASPERS, VANDENBURGH &
LINDQUIST, P.A.

225 South Sixth Street, Suite 4200

Minneapolis, MN 55402

Telephone: (612) 436-9618

Facsimile: (612) 436-9605

Email: dvandenburg@carlsoncaspers.com

Lead Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on October 20, 2025 a complete copy of the foregoing Petitioner's Request for Director Review of Decision Denying Institution of *Inter Partes* Review served electronically on Patent Owner's counsel of record at the below. Patent Owner's counsel agreed to dispense with service of paper copies.

Shashank Upadhye, Reg. No. 48,209 Upadhye Tang LLP 109 Symonds Dr. #174 Hinsdale, IL 60522-0174 312-327-3326 shashank@ipfdalaw.com <i>Lead Counsel</i>	Brent Batzer Reg. No. 66,130 Upadhye Tang LLP 109 Symonds Dr. #174 Hinsdale, IL 60522 312-598-2612 brent@ipfdalaw.com Yixin Tang Upadhye Tang LLP 109 Symonds Dr. #174 Hinsdale, IL 60522 312-598-2611 yixin@ipfdalaw.com <i>Back-up Counsel</i>
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/s/ J. Derek Vandenburg/

J. Derek Vandenburg
Registration No. 32,179