

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICALS INDUSTRIES INC.,

Petitioner

v.

NIVAGEN PHARMACEUTICALS, INC.,

Patent Owner

IPR2025-00893

Patent No. 11,878,076

**PATENT OWNER'S AUTHORIZED RESPONSE TO
DIRECTOR REVIEW REQUEST**

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Patent Owner Nivagen Pharmaceuticals, Inc. (“Patent Owner” or “Nivagen”) states the following in response to Petitioner Sun Pharmaceutical Industries, Inc.’s (“Petitioner’s” or “Sun’s”) Director Review Request (“Request,” Paper 19) for the Director to review and vacate the Director’s Discretionary Decision Denying Institution (“Decision,” Paper 18):

I. INTRODUCTION

Sun is asserting a narrow construction of the term “composition” in parallel district court proceedings while asserting a broader construction here in its Petition. It is not hard to understand why: Sun wants two bites at the apple, without any regard to the correctness of its directly contradictory claim construction positions. The Acting Director, exercising her discretionary authority, determined that the Board’s resources are better spent on cases where a petitioner is not seeking an unprincipled tactical advantage. That decision is correct—no matter the standard the Director employs now on review.

But standards matter, although Sun does not address them. Sun treats this review as if it were a do-over by proffering new reasons it never presented to oppose discretionary denial. The current guidance requires Sun to show the Acting Director missed something, not just reargue prior points or assert new ones. Sun’s complaints are a futile exercise under the operative standards—*i.e.*, Sun does not even attempt to find a point that the Acting Director overlooked or misapprehended. The closest

that Sun comes—contending that operative guidance provides no notice that the Acting Director may consider claim construction issues—is both factually wrong (the Acting Director did not make any claim construction determinations) and meritless anyway (the relevant guidance permits merits to inform the discretionary aspects of institution decisions).

Unable to meet the rehearing standard for the issues that bore on the discretionary denial, Sun seeks to attack the Acting Director’s authority to have issued a decision. Sun supplies no legal support and bluntly asserts “facts” without record evidence. But even were one to overlook these procedural infirmities, Sun’s argument fails because it rests on a bad premise: that the Director’s confirmation, on its own and effective immediately, removed the Acting Director’s authority to issue the Decision.

Finally, Office guidance counsels that requests to rehear the Director’s decisions “should be rare ... and only for very focused purposes.” Director Review Process (<https://www.uspto.gov/patents/ptab/decisions/director-review-process>), at Part 5.C.ii. Sun’s request—a losing party’s routine attempt to reargue merits and advance new points it could have made—shows why these ought to be the exception. The Request should be denied.

II. REASONS TO DENY REQUEST FOR FURTHER DIRECTOR REVIEW

A. Sun's Request Fails Because Sun Does Not Raise Arguments Even Attempting to Satisfy the High Bar for Rehearing.

“A party dissatisfied with a Director Review decision ... carries the burden of showing the Director Review decision should be modified.” Director Review Process, at Part 5.C.ii.¹ To meet this burden, “the rehearing request must specifically identify what matter the Director Review decision misapprehended or overlooked.” *Id.* Importantly, a “request for rehearing of a Director Review decision is **not** an opportunity to raise new issues, reargue issues, or disagree with determinations by the Director.” *Id.* (emphasis added). “The Director will not consider new evidence or new arguments not part of the official record,” except if expressly authorized in “cases addressing issues of first impression or issues involving intervening changes in the law or USPTO procedures, guidance, or decisions.” *Id.* at Part 3.E.

Sun's rehearing request argues (1) that the Acting Director improperly considered purportedly non-discretionary claim construction issues when exercising her discretion (Request at Part IV.A); (2) that, even if the Acting Director properly considered such issues, the Director should find that Sun's reasons for advancing

¹ The Director should employ the same standards to the Request that apply to requests for rehearing of other types of Director Reviews.

different claim construction positions in the two forums are substantially justified (Request at Part IV.B); and (3) that the Acting Director should not have issued the Decision in light of the Director's confirmation (Request at Part IV.C). None comply with applicable standards for Director review because none identify subject matter that the Acting Director "misapprehended or overlooked."

On the first and second arguments, Sun had the chances in its opposition to Nivagen's discretionary denial request both to contend that the Acting Director could not consider Sun's inconsistent claim construction positions as part of her discretion and to present to the Acting Director *why* it advances inconsistent claim construction positions. After all, Nivagen squarely presented Sun's gamesmanship in its request. *See* Paper 7, at 5, 6 n.2, 31–32. Yet Sun did not so argue, and so its claim now presents a prohibited "new issue." By definition, the Acting Director "could not have overlooked or misapprehended an argument which was not before" her. *Ex Parte Quist*, 95 U.S.P.Q.2d 1140, at *3 (B.P.A.I. 2010). And to the extent that Sun argues the Acting Director misweighed Sun's inconsistency, its contention amounts to a disagreement with the Acting Director's determination, which does not meet the rehearing standard either.

Sun's third argument (Issue IV.C) was indisputably not raised before the Decision issued (nor could it have been). And it relies on factual assertions with no record support. Per the applicable guidance, a rehearing request may not raise new

issues and evidence without preauthorization. Nothing reflects that Sun sought or obtained such preauthorization, so this argument too is procedurally improper. Sun's noncompliance with the rehearing standard suffices to deny further review.

For the most part, Sun treats its request as if review were *de novo*, which as just explained, does not conform to the relevant guidance. But sometimes Sun refers to the Decision as an "abuse of discretion." *E.g.*, Request, at 6, 8, 11. Nivagen disagrees that "abuse of discretion" is a valid ground for rehearing, but in any event, Sun ignores that the Office's institution discretion is nearly limitless. Under 35 U.S.C. § 314(a), "the PTO is permitted, ***but never compelled***, to institute an IPR proceeding." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (emphasis added); *see Cuozzo Speed Techs. v. Lee*, 579 U.S. 261, 273 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."). The Interim Director Discretionary Process Guidance expressly left available to the Acting Director consideration of the full panoply of relevant evidence and arguments bearing on her discretion. *See infra* at 10 (describing Process Guidance's retention of wide discretion to consider nearly any factor bearing on institution). The Office's discretion is so sweeping as to allow institution denials for reasons divorced from a petition's individual circumstances, such as workload issues. *See, e.g.*, Mar. 26, 2025 Mem. from Acting Director Stewart to All PTAB Judges, at 3 ([5](https://www.uspto.gov/sites/default/files/documents/InterimProcesses-</p></div><div data-bbox=)

PTABWorkloadMgmt-20250326.pdf) (“Process Memorandum”) (explaining the Director will consider “the ability of the PTAB to comply with pendency goals for *ex parte* appeals, its statutory deadlines for AIA proceedings, and other workload needs.”); Interim Director Discretionary Process Guidance, at Part I.A. (<https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>) (“Process Guidance”) (describing as potential factors in institution decision “facts and circumstances within the purview of the Office or Office operations that the parties are not in a position to raise” and “considerations enumerated in the Process Memorandum”). Given the discretion the Office guidance afforded the Acting Director in deciding whether to institute, as further explained below, Sun’s garden-variety complaints do not overcome this heavy burden.

B. The Acting Director’s Decision Denying Institution Correctly Evaluated the Relevant Factors.

1. Contrary to Sun’s Argument, the Decision Identifies Other Bases as Supporting Non-Institution.

Sun premises its argument on mistaken footing: that the Decision’s conclusion about Sun’s inconsistent claim construction positions was “[t]he only factor identified as favoring discretionary denial.” Req. at 6. Yes, Sun’s hypocrisy was the Decision’s principal basis and the only denial factor receiving extended treatment. But the Decision also repeatedly eschews cabinining itself to only those issues that were expressly analyzed: (1) “[D]iscretionary denial of institution is appropriate in

this proceeding ... based on the totality of the evidence and arguments the parties have presented” “in view of all relevant considerations.” Decision at 2; (2) “Although certain arguments are highlighted above, the determination to exercise discretion to deny institution is based on a holistic assessment of all of the evidence and arguments presented.” *Id.* at 3; (3) “Other factors_s, however, favor discretionary denial.” *Id.* at 2 (emphasis added); and (4) “The considerations_s favoring denial, therefore, outweigh the considerations that counsel against it.” *Id.* at 3 (emphasis added).

Nivagen set out many reasons for denying institution that the Decision does not expressly address. For example, Nivagen explained that (1) Sun also asserts each of the Petition’s grounds in the district court case (Paper 7 at 17–28); (2) the parties and a court had already expended significant resources in litigation (*id.* at 16–17); and (3) Sun had not actually committed to a *Sotera* stipulation (*id.* at 28–29), leaving open the possibility of conflicting results and duplicative proceedings. By the Decision’s own language, these issues weighed into circumstances the Acting Director considered when denying institution.

As a non-appealable decision in which the Office is vested nearly unlimited discretion, institution denials need not be show-and-tell exercises. *See Murata Manufacturing Co., Ltd, v. Georgia Tech. Res. Corp.*, IPR2025-00383, -00384, Paper 17, at 2 (Dir. Oct. 15, 2025) (on Director review denying rehearing, supporting

initial discretionary denial decision based on “additional factors not highlighted in the original discretionary denial decision”). In fact, going forward, such decisions will be summary notices unless they present novel or important issues. *See* Oct. 17, 2025 Mem. from Director Squires to All PTAB Judges, at 2 (https://www.uspto.gov/sites/default/files/documents/open-letter-and-memo_20251017.pdf). The Acting Director appropriately exercised discretion in light of many considerations, not just the one that Sun specifically takes issue with.

2. The Decision Appropriately Denies Institution Based on Sun’s Inconsistent Positions, Not on the Merits of Sun’s Claim Construction Position.

Sun’s principal argument that the Acting Director abused her discretion by considering the merits of Sun’s claim construction position in violation of the Practice Guide rests on a fallacy: that the Acting Director considered the merits of Sun’s position. To the contrary, the Acting Director appropriately considered the conflict in position that Sun advances in two forums for its own strategic benefit.

According to Sun, the Decision found that there was a “failure by Petitioner to ‘sufficiently explain’ in the *discretionary* briefing its claim construction position for the term ‘composition’ in this IPR.” Req. at 6. That mischaracterizes and misuses the Decision’s quoted language. Here is what the Decision actually says: “Petitioner does not sufficiently explain why it advanced a narrow construction in district court and advances a broader construction in the Petition.” Decision at 3. The criticism is

not about the merits of the claim construction position, but rather, Sun’s choice not to justify its irreconcilable yet simultaneously advanced positions.

Sun’s attempt to transform the Decision’s recognition of the unfairness from instituting based on Sun’s *inconsistency* into merits consideration of claim construction does not survive scrutiny. The Decision does not analyze the correctness of Sun’s district court claim construction position, its IPR claim construction position, or Nivagen’s positions. As Sun states, no claim construction dispute existed in the four corners of the IPR, as both Sun and Nivagen agree here that plain and ordinary meaning was the correct claim scope. Sun does not and cannot explain how, in a case where claim construction was not disputed, the Decision is based on considering the merits of claim construction positions.

Nor was Sun “penalized” for identifying no claim construction issues. Req. at 8. IPR institution denial is not a punishment; it is the Director’s exercise of discretion about how to allocate the Office’s resources. That said, the Decision’s result recognizes the unprincipled nature of Sun’s two-forum, irreconcilable-argument strategy that the Office’s adoption of the *Phillips* standard sought to curb: “patent infringers ... aggressively argu[ing] inconsistent positions on claim scope in different forums with impunity—a broad scope before the PTAB, and a narrow scope before the district court.” *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal*

Board, 83 Fed. Reg. 51340, 51350 cmt. 8 (Oct. 11, 2018); *see also* Decision at 3.

Sun tries to cover over its inconsistent positions by blaming the Process Guidance, which, according to Sun, permits consideration of “claim construction issues” only during non-discretionary review. Req. at 6–7, 8–9. *First*, since no one claims Sun violated any rule or mandatory obligation by contending that “no express construction was required,” no conflict with the Practice Guide exists. The Acting Director understood, however, that justice does not tolerate a party staking out opposing decisions, hoping that one might prevail, unless valid reasons justify the discrepancy. *Second*, and perhaps more importantly, to claim lack of notice, Sun ignores the Process Guidance’s text describing “discretionary considerations.” *See* Req. at 7. Part I.B. of the Process Guidance invites movants to “address all relevant considerations,” “encourage[s]” parties to “address any fact or circumstance they believe bears on the Director’s discretion to institute,” identifies enumerated considerations as “non-exhaustive” and “exemplary,” and explains that the Director will consider “[a]ny other considerations bearing on the Director’s discretion.” In this case, the Acting Director’s evaluation of Sun’s inconsistency was unsurprising; Nivagen’s discretionary denial request raised the issue. *See* Paper 7, at 5, 6 n.2, 31–32. Sun substantively responded, though it never claimed that Office guidance barred the Acting Director from addressing the matter, nor that Sun had good reasons for asserting its inconsistent positions. *See* Paper 14, at 27–29. The Acting Director

correctly adopted Nivagen’s arguments, consistent with Office guidance.

Sun’s reliance on case law about the role of claim construction positions does not save its request. *Dish Network*, *Samsung Electronics*, and *10X Genomics*² all stand for a proposition not relevant here: that the Petition is not deficient under the Office’s regulations (37 C.F.R. 42.104(b)) and does not constitute an automatic failure of proof under 35 U.S.C. § 314(a)’s “reasonable likelihood” standard because it advances a claim construction different than what Sun presented to the district court. *Compare* Req. at 9 *with* cited decisions. The Acting Director did not find the Petition violated any rules or substantively failed. Even assuming “[t]here is nothing to prevent a petitioner from advancing one construction in the District Court as an infringement defendant and a different construction as a Petitioner before the Board,” *Samsung Elecs. Co. v. Smart Mobile Techs. LLC*, IPR2022-01248, Paper 13 at 58 (P.T.A.B. Jan. 24, 2023), there is also nothing stopping the Acting Director from weighing Sun’s tactical decision when determining whether the

² Notably, *10X Genomics* distinguishes the institution denial in *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 (P.T.A.B. Mar. 1, 2019), because in *OrthoPediatrics*, “the petitioner took conflicting positions between the IPR proceeding and the related district court litigation.” *10x Genomics, Inc. v. Bio-Rad Lab’ys, Inc.*, IPR2020-00086, Paper 8 at n.8 (P.T.A.B. Apr. 27, 2020).

Office should devote its resources to adjudicating the Petition. To the contrary, the Board has before discretionarily denied institution based on the inconsistency of a petitioner's claim construction positions under *Fintiv* Factor 6. *E.g.*, *Kiosoft Techs., LLC v. Payrange Inc.*, No. IPR2021-00086, 2021 WL 1096966, at *7 (P.T.A.B. Mar. 22, 2021). *Cambridge Mobile v. Telematics* also supports the commonsense logic that a petitioner must explain its inconsistent claim construction positions to avoid the reasonable damage to credibility that such insincerity naturally carries. IPR2024-00966, Paper 12, at 8 (P.T.A.B. Dec. 13, 2024) ("the Petition should have explained ... why the inconsistent positions are warranted"). The Director's consideration of Sun's contradictory positions was appropriate.³

3. Sun's Complaints of Unfairness Result from Its Own Strategic Gamble, Not the Rules Governing IPRs.

Sun raises a Halloween-timed scarecrow—being forced to choose between disclaimer and the ability to seek Board review. *See* Req. at 14. But Sun had a third option: It could have consistently advanced one claim construction position in both forums, as Nivagen has done. Sun chose not to do so, but pressed on with contradictory positions no matter their objective correctness.

³ This is true even if the Acting Director considered the merits, because Part I.B. of the Process Guidance permitted her to consider "[t]he strength of the unpatentability challenge" as a discretionary factor.

Sun's "dilemma" is simply not being permitted to eat the cake and have it too.

If Sun thought that its disclaimer position was too weak to convince the Board under the same standards a district court applies, Sun should rethink advancing it in district court. The converse is also true: if Sun believes in its disclaimer position but did not want to advance it here (perhaps because it does not believe it has a case of Section 102/103 invalidity based on the narrowed scope), Sun should not have wasted everyone's resources by filing an IPR at the deadline with a claim construction position it elsewhere contends is wrong. This dichotomy highlights the correctness of the Acting Director's implied conclusion that allowing Sun to proceed in two forums simultaneously arguing that the exact same claim term means two different things without explanation damages the integrity of the patent system and wastes resources. With the Board and the district court both applying *Phillips*, a party's position on claim construction should not wobble so much. *See* 37 C.F.R. § 42.100(b); *see also* 83 Fed. Reg. at 51350 cmt. 8 ("With a uniform application of the *Phillips* standard, patent challengers will have less flexibility to advance inconsistent arguments about claim scope, and will instead be required to choose a single claim construction that best captures the true meaning of the patent claim.").

Lastly, Sun's claims that its inconsistency does not implicate uniformity, predictability, and efficiency and that it is not seeking construction of "composition" misread the risk here. First, Sun *is* seeking to invalidate patent claims by *applying*

plain and ordinary meaning here, even if it is not so advocating. And second, if the IPR were instituted here (applying a plain-and-ordinary meaning construction) **and** the court were to adopt Sun’s disclaimer argument, one proceeding will have been a wasteful exercise under an incorrect claim construction. Sun really is trying to have it both ways—at the Office’s, the district court’s, and Nivagen’s expense.

C. Sun’s Argument Regarding the Appropriateness of the Interim Director’s Adjudication is Cursory, Unsupported, and Wrong.

Without any legal or factual support, Sun claims that the Acting Director should not have issued the Decision because the current Director, John Squires, had been Senate-confirmed when the Decision issued (and thus, Sun implies, should have decided the discretionary issues as Director). *See* Req. at 15. Sun’s argument is easily rejected because it ignores the dispositive fact that Squires was not yet Director when the Decision issued.

The Senate confirmed Squires as Director on September 18, 2025. *See PN26-44 - Nomination of John Squires for Department of Commerce*, 119th Congress (2025-2026), PN26-44, 119th Cong. (2025) (<https://www.congress.gov/nomination/119th-congress/26/44>). But confirmation alone did not make Squires the Director; rather, he became Director only after the President signed his commission and he swore his oath of office. *See* U.S. Const., Art. VI, Cl. 3 (“[A]ll executive ... Officers ... shall be bound by Oath or Affirmation, to support this Constitution.”); 5 U.S.C. §§ 2901–2903; *id.* § 1331; *Dysart v. United*

States, 369 F.3d 1303, 1306 (Fed. Cir. 2004) (describing appointment process); *see also Appointment and Confirmation of Executive Branch Leadership: An Overview*, Cong. Res. Serv. Rpt. R44083, at 6 (2021) (<https://www.congress.gov/crs-product/R44083>) (“In the final stage of the appointment process, the confirmed nominee is given a commission signed by the President ... and sworn into office. ... Once the appointee is given the commission and sworn in, he or she has full authority to carry out the responsibilities of the office.”). Director Squires was sworn in on September 22, 2025—3 days after the Acting Director discretionarily denied institution here. *See* Sept. 23, 2025 Press Release (<https://www.uspto.gov/about-us/news-updates/ceremonial-swearing-remarks-john-squires>). Accordingly, the Acting Director headed the Office until Director Squires was sworn in, and thus, the Director could not have issued the discretionary denial as Sun suggests.

III. CONCLUSION

Nivagen requests that the Director deny rehearing outright, or purely as a practical exercise to obviate any argument about the Acting Director’s authority, grant rehearing and reissue the same decision under the Director’s authority. If the Director is inclined to grant rehearing for other reasons, the Director ought to first consider based on the totality of the record whether discretionary denial remains appropriate, and if not, then determine whether the Petition satisfies the non-discretionary standard for institution before instituting.

Respectfully Submitted,

Dated: October 27, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on August 18, 2025, I caused a complete copy of the foregoing Patent Owner's Authorized Response To Director Review Request to be served on Petitioner's counsel of electronically to counsel of record for Petitioner at at least the following email addresses upon agreement of the parties:

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