

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BPI LABS, LLC,
PETITIONER,

v.

ELI LILLY AND COMPANY
PATENT OWNER.

Case IPR2025-01346
Patent 9,474,780

**PETITIONER BPI LABS, LLC'S REQUEST FOR DIRECTOR REVIEW
OF DECISION DENYING INSTITUTION**

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I. INTRODUCTION

BPI Labs, LLC (“Petitioner”) respectfully requests Director Review of the December 11, 2025 Notice denying institution of IPR2025-01346 (“Denial Decision”) “[p]ursuant to 35 U.S.C. § 314(a), after a review of discretionary considerations”. See Paper No. 10, Notice of Decisions on Institution at 1. A Director Review may reconsider “any decision on institution under 35 U.S.C 135, 314, or 324.” 37 CFR § 42.75. A Director Review is appropriate here for at least two reasons: (1) to correct material errors and avoid inconsistent outcomes with IPR2025-01024 in which a pending Director Review is currently reconsidering a discretionary denial based on similar issues raised by Patent Owner in the present IPR and (2) to address deficiencies of the Denial Decision in light of the Administrative Procedure Act (APA).

II. DISCRETIONARY DENIAL WARRANTS DIRECTOR REVIEW BECAUSE IT RESTS ON MATERIAL ERROR AND RISKS INCONSISTENT APPLICATION WITH THE PENDING DIRECTOR REVIEW IN IPR2025-01024

The Denial Decision provides no case-specific explanation for denial beyond stating that institution is denied after review of discretionary considerations. The discretionary issues raised by Patent Owner in this proceeding substantially overlap with those raised in *Empower Clinic Services, LLC v. Eli Lilly & Co.*, IPR2025-01024 (challenging the same ’780 patent), which was discretionarily denied on October 10, 2025 (IPR2025-01024, Paper 15) and is currently the subject of a

pending request for Director Review (IPR2025-01024, Paper 16). The Director authorized a Patent Owner response in that matter (IPR2025-01024, Ex. 3103), and Patent Owner filed its response (IPR2025-01024, Paper 17). Consistent treatment of materially similar records, and correction of material factual or legal error, warrants Director Review here.

Petitioner has identified material errors similar to those identified in IPR2025-01024. In particular, Patent Owner should not receive the benefit of a discretionary denial of this IPR given Patent Owner's failure to inform the examiner of material teachings of Patent Owner's prior application, exacerbating the issuance of defective patents. Furthermore, the Patent Owner's purported evidence about investments cited in the Empower IPR Denial lack any nexus to the '780 Patent.

Finally, the Director should grant this Director's Review to avoid conflicting outcomes with IPR2025-01024 based on substantially similar facts.

A. Material Errors in Prosecution Due to Patent Owner's Failure to Inform Examiner of Relevant Information About its Own Earlier Patent Defeats any § 325(d) or *Advanced Bionics* Basis for Discretionary Denial

Patent Owner urged discretionary denial under 35 U.S.C. § 325(d), contending that Petitioner's asserted references and arguments were previously presented to the Office and that Petitioner failed to show any material examination error. But even if *Advanced Bionics* step 1 were satisfied as to certain art, discretionary denial is inappropriate where the record demonstrates an Office error

material to patentability under *Advanced Bionics* step 2.

It is actions like those taken by Patent Owner during prosecution of the '780 Patent that exacerbates the defect rate in issued patents. As explained in Petitioner's opposition to discretionary denial, Patent Owner did not inform the examiner of the materiality of its own earlier patent application, *Alsina-Fernandez*. See Ex. 1007, p. 15-17. In particular, the examiner found the claims patentable because the art the examiner was considering lacked a glutamine at position 24. Yet, Patent Owner was aware that its own prior patent, *Alsina-Fernandez*, disclosed that very feature.

Patent Owner downplays the materiality of its silence by arguing that *Alsina-Fernandez* appears in the hundreds of pages of disclosures and search reports, and thus this critical teaching in *Alsina-Fernandez* of a glutamine at position 24 is technically "considered" by the examiner. See Patent Owner Discretionary Denial Brief at 10-11. While this legal fiction that an examiner would find the proverbial needle in a haystack may satisfy Patent Owner's duty of candor during prosecution, this behavior should not be further rewarded with a denial of this IPR. If not for the IPRs filed against the '780 Patent, the Office would not be aware that the reason for allowance was known in the prior art, a fact that Patent Owner knew well yet remained silent on.

By denying this IPR, the Director sends a message that patent applicants are free to remain silent even when they know an examiner has overlooked material

teachings in the prior art. Instead, the Director should institute this IPR to incentivize patent applicants to be more forthcoming during prosecution so that the Office does not need to learn of material information only via third parties after a patent has already issued. Doing so would increase the robustness of the prosecution process and reduce the risk of defective patents issuing, such as the '780 Patent, which was never examined with awareness that relevant prior art taught glutamine at position 24.

Under *Advanced Bionics* step 2, the Office allowed the claims based on a factual predicate (e.g., absence of a teaching/suggestion for Gln24) that is contradicted by the prior art disclosure Petitioner relies upon. Accordingly, Section 325(d) cannot support discretionary denial on this record, and the Petition should be referred for merits consideration in the normal course.

B. The Record Does Not Support “Settled Expectations” Because Patent Owner Has Not Shown Its Alleged Investments are Directed to the Challenged '780 Claims

Patent Owner’s purported investments in clinical trials, accepted in the Empower IPR Denial, lacks any nexus to the challenged '780 patent. *See e.g.*, IPR2025-01024, Paper 15 (“In particular, Patent Owner has conducted 83 clinical trials involving tirzepatide.”). Patent Owner made substantially the same argument about clinical trials in this proceeding. Paper No. 6 at 7, (“Lilly has conducted over 80 tirzepatide clinical trials, all aimed at showing that its patented invention is safe

and/or effective.”). Yet, reliance on this fact is material error because Patent Owner has not explained the alleged nexus between the challenged patent to these clinical trials.

The Discretionary Denial overlooked the significance of this missing nexus. Patent Owner is attempting to manufacture “settled expectations” for the challenged patent based on investments in trials that encompass different, unrelated patents alleged to cover tirzepatide, including patents that issued in 2025. *See* Ex. 2044 (tirzepatide Orange Book entry listing US Patent Nos. 12,295,987 and 12,343,382).¹ Lilly’s attempt to allocate investments supporting these recently issued patents to the challenged patent is improper and cannot support settled expectations.

C. “Settled Expectations” for Patents on FDA-Approved Medications Differs from Other Industries

The Discretionary Denial also erred by failing to account for the fact that the challenged patent relates to an FDA-approved medication, where settled

¹ The fact that the challenged patent is listed in the Orange Book for Lilly’s tirzepatide product cannot establish nexus because the Orange Book listing is a routine, unilateral assertion by Patent Owner rather than a finding by the FDA. *Teva Branded Pharm. v. Amneal Pharms.*, 124 F.4th 898, 904-06 (Fed. Cir. 2024) (“When an [NDA] holder that owns a patent-submits an NDA, it must submit information on ‘the patent number and expiration date of each patent’” where “the FDA does not police this process”).

expectations are vastly different from other industries. As explained more fully in Petitioner's Opposition [ADD CITE], using the patent issue date to measure the passage of time for settled expectations is impractical in the pharmaceutical industry, where the Hatch-Waxman Act provides marketing exclusivities before follow-on products can be approved and proscribes the timing of FDA submission and court challenges to patents. Here, the '780 Patent was issued in 2016, but tirzepatide received FDA approval in May 2022 and was awarded NCE exclusivity, precluding any FDA filings by potential generic challengers (and thus the start of any patent challenges under the Hatch-Waxman process) until May 2026 at the earliest. Yet, the Discretionary Denial does not account for these statutory bars to patent challenges.

Instead, Patent Owner's settled expectations argument immunizes Orange Book patents from any practical challenge for years, artificially driving up drug prices, contrary to the Administration's goals. *See* Paper 8 at 7-8; *see also* Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, 90 Fed. Reg. 16441 (2025) ("It is the policy of the United States that Federal...intellectual property protections...are optimized to provide access to prescription drugs at lower costs to American patients and taxpayers.").

D. The Prior Petition by Empower Does Not Justify Denial of an Independent Challenge, and Consistency Warrants Review While IPR2025-01024 Is Pending

Patent Owner urged denial on the ground that this Petition is “redundant” to Empower’s earlier petition. But the existence of a prior petition filed by a different petitioner is not, by itself, a sound basis to bar an independent challenge, particularly where the earlier outcome was a discretionary denial rather than an adjudication of patentability. Absent a showing of privity, abuse, or unfair “roadmapping,” denying institution solely because another party previously filed would improperly convert discretionary denial into de facto immunity from further review. Moreover, consistency warrants Director Review while IPR2025-01024 is pending.

III. DISCRETIONARY DENIAL FAILS TO COMPLY WITH THE APA

The Denial Decision should be reviewed because it is based on the promulgation of new institution rules by the Director without going through the notice-and-comment rulemaking process required by the APA. *See* 5 U.S.C. § 553. The Federal Circuit has recently confirmed that such challenges are reviewable under the APA. *See Apple Inc. v. Vidal*, 63 F.4th 1, 14 (Fed. Cir. 2023) (“Plaintiffs’ third challenge is that the Director was required, by 35 U.S.C. § 316 together with 5 U.S.C. § 553, to promulgate the institution instructions through notice-and-comment rulemaking procedures. This challenge, we conclude, may be pressed under the APA.”).

In addition, the summary denial issued in this proceeding likewise runs further afoul of the APA because it fails to provide “a full and reasoned explanation of its decision” for a reviewing court to consider in determining if the Denial Decision runs afoul of the APA. *See* 5 U.S.C. § 706(2); *Personal Web Technologies, LLC v. Apple, Inc.*, 848 F.3d 987, 992 (2017) (“For judicial review to be meaningfully achieved within these strictures, the agency tribunal must present a full and reasoned explanation of its decision.”) (quoting *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002)).

A. The Denial Decision is Based on New Rules Implemented Without Notice and Comment

1. *APA requires notice and comment for new rules*

Under the APA, an agency may adopt rules—other than policy, interpretative, or procedural rules—only through notice-and-comment rulemaking. 5 U.S.C. § 553. That procedure requires the agency to “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments” before the rule is adopted and to consider and respond to significant comments received during the comment period. *Id.* at § 553(c); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The notice-and-comment process reflects Congress’s “judgment that notions of fairness and informed administrative decision making require” agency decisions to be made “only after affording interested persons notice and an opportunity to comment.”

Chrysler Corp. v. Brown, 441 U.S. 281, 316 (1979).

2. *Director’s discretionary denial factors are a new rule*

The APA defines a “rule” as an “agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy.” 5 U.S.C. § 551(4). Courts “generally refer[] to the category of rules to which the notice and comment requirements ... apply” as “substantive” or “legislative” rules. *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014).

A “substantive” rule is “one that effects a change in existing law or policy which affects individual rights and obligations.” *In re Chestek PLLC*, 92 F.4th 1105, 1109 (Fed. Cir. 2024) (quotation marks omitted); *see also Chrysler*, 441 U.S. at 302 (a substantive rule “affect[s] individual rights and obligations”). A substantive rule, in other words, “grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests.” *Batterton v. Marshall*, 648 F.2d 694, 701-702 (D.C. Cir. 1980). Notice and an opportunity to be heard are required when a rule affects private rights and interests. *See Chrysler*, 441 U.S. at 316.

Here, on October 17, 2025, the Director issued a memo about institution decisions using an approach to institution denials that “flows from the processes outlined in the March 26, 2025 memorandum entitled ‘Interim Processes for PTAB Workload Management’ (‘Interim Processes’), under which the Director determines whether or not to deny a petition based on discretionary considerations.”

Memorandum entitled Director Institution of AIA Trial Proceedings at 1, issued October 17, 2025 (“Director Institution Memo”) (omitted footnote provides webpage to access the Interim Processes memo)²; *id.* at 2 (Interim Processes memo provides “substantial guidance on how the Director will handle discretionary considerations.”). As such, even though the Denial Decision in this IPR does not provide specific fact findings, the Director Institution Memo makes clear that the factors utilized to make the decision encompass substantially the same factors laid out in the Interim Processes memo.

The Interim Processes memo lays out numerous factors that can be considered when denying an IPR petition including:

- Whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims;
- Whether there have been changes in the law or new judicial precedent since issuance of the claims that may affect patentability;
- The strength of the unpatentability challenge;
- The extent of the petition’s reliance on expert testimony;
- Settled expectations of the parties, such as the length of time the claims have been in force;
- Compelling economic, public health, or national security interests; and

² Available at https://www.uspto.gov/sites/default/files/documents/Director_Institution_of_AIA_Trial_Proceedings.pdf.

- Any other considerations bearing on the Director’s discretion.

Interim Processes at 2-3. These factors that result in denial of IPR institution were issued to “All PTAB Judges” and placed into effect immediately without any formal notice and comment period for the public. *See* Director Institution Memo at 1; Interim Processes at 1.

The Director Institution Memo constitutes a substantive rule because it “produce[s] ... significant effects on private interests.” *See Batterton*, 648 F.2d at 702. In addressing a prior similar discretionary denial procedure based on the Board’s *Fintiv* decision, the Federal Circuit already held that instructions that are likely to produce more denials of institution than might otherwise occur harms private IPR petitioners. *Apple Inc. v. Vidal*, 63 F.4th 1, 16-17 (Fed. Cir. 2023); *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (Mar. 20, 2020) (precedential); *see also* Interim Process memo at 2 (relying in part on the *Fintiv* rationale).

Importantly, the Director Institution Memo, like the *Fintiv* instructions discussed in *Apple Inc. v. Vidal*, would cause more denials of IPRs when any of the enumerated denial factors exist, thus restricting private parties of the opportunity to seek cancellation of questionable patent claims in IPR. *Apple*, 63 F.4th 1, 17. Indeed, the Federal Circuit noted that *Fintiv* denials caused “more denials of institution than might otherwise occur[.]” *Id.* There is no question that the factors adopted in the Director’s Institution Memo are even more restrictive given that the *Fintiv* rationale

is just one of multiple possible denial factors outlined in the Memo. Interim Process at 2. The Federal Circuit further explained that *Fintiv* denials “threaten[s] ... harm” to the “legally protected interest” of private parties by reducing the likelihood that they can pursue IPR. *Id.* at 16. Finally, the Federal Circuit recognized “the realistically perceived advantages of the IPR process,” such as reduced costs, statutory deadlines, and a lower burden compared to district court. *Id.* at 17.

The increased chance of denial and loss of the benefits of IPR is of particularly relevance in the instant case, where IPR “is the only currently available adversarial proceeding” for Petitioner to challenge the ’780 Patent. See Petitioner’s Discretionary Denial Opposition, Paper No. 8 at 6-7. The lack of viable alternatives further demonstrates that the factors limiting institution set out in the Director Institution Memo are substantive rules that produce a significant effect on Petitioner’s private interest in determining the patentability of the ’780 Patent.

In addition, the Director Institution Memo is a substantive rule because it makes it harder to obtain a benefit even though the benefit (i.e., the institution decision) is discretionary. For example, the D.C. Circuit has made it clear that policies that alter the standards a parole board applies, making it harder to obtain parole, are substantive rules subject to notice and comment even though parole decisions are imbued with the parole board’s discretion. See *American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987) (citing *Pickus v. United States Bd.*

of Parole, 507 F.2d 1107, 1113 (D.C. Cir. 1974)). As the D.C. Circuit later explained, the rule altering the parole board’s standards was subject to notice and comment not because inmates had an “existing right” to parole, but because the changes in parole standards were “calculated to have a substantial effect on ultimate parole decisions.” *American Hosp. Ass’n*, 834 F.2d at 1046.

Here too, the Director Institution Memo has a substantial effect on ultimate institution decisions and makes it less likely a private party’s IPR petition will be instituted. The Director Institution Memo is designed to further limit access to the benefits of IPR by including many factors beyond those espoused in *Fintiv*. This process affects IPR petitioners’ private interests even though a petitioner may have no entitlement to IPR. Notice-and-comment rulemaking is required in such circumstances to ensure that those who will be affected have an opportunity to be heard and that the agency benefits from their perspective. *See Small Refiner*, 705 F.2d at 547. These considerations plainly apply where, as here, the rule altered the agency’s decisions, causing the agency “to deny benefits in close cases where benefits might previously have been granted.” *Id.* at 1505.

Finally, the America Invents Act expressly incorporates the APA’s notice-and-comment requirements by providing that the Director adopt certain types of generally applicable rules governing IPR, if at all, by “prescrib[ing] regulations.” 35 U.S.C. § 316(a). Congress’s use of the term “regulations” generally denotes

“legislative [i.e., substantive] rules” rules issued after notice and comment. *United States Telecom Ass’n v. FCC*, 400 F.3d 29, 38 (D.C. Cir. 2005). The requirement to proceed by “prescrib[ing] regulations” applies specifically to rules “setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a).” 35 U.S.C. § 316(a)(2). This provision provides evidence of Congress’s understanding that rules setting institution standards are substantive rules beyond the scope of the Office’s pre-existing procedural rulemaking authority.

Therefore, the process laid out in the Director’s Institution Memo (based on the Interim Process memo) are substantive rules that require notice and comment before being promulgated and adopted.

B. The Denial Decision Fails to Provide a Full and Reasoned Explanation for a Reviewing Court to Consider APA Violations

Although the decision to institute is generally unreviewable, the Supreme Court and Federal Circuit have found limited exceptions grounded in APA violations when the decision fails to provide a full and reasoned explanation for the denial. *Personal Web.*, 848 F.3d at 992 (“For judicial review to be meaningfully achieved within these strictures, the agency tribunal must present a full and reasoned explanation of its decision.”); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1322 (Fed. Cir. 2016) (the USPTO must “provide an administrative record showing the evidence on which the findings are based, accompanied by the agency’s reasoning in reaching its conclusions.”). Here, the Denial Decision provides no

explanation or administrative record showing why the Director exercised discretion to deny the instant IPR.

Moreover, the Supreme Court has noted that despite the “no appeal” provision of 35 U.S.C. § 314(d), a party can still seek review where a party alleges the USPTO exceeds its statutory bounds or other limited challenges. *SAS*, 584 U.S. 357, 371 (“If a party believes the Patent Office has engaged in ‘shenanigans’ by exceeding its statutory bounds, judicial review remains available consistent with the Administrative Procedure Act,...”); *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 266, 275 (unreviewability provision of § 314(d) may not bar “appeals that implicate constitutional questions, that depend on other less closely related statutes, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond ‘this section.’”).

Given the possibility of review under the APA, the Director should reconsider the Denial Decision to provide a full and reasoned explanation of its decision denying this IPR. This is required to permit a reviewing court to determine if the Denial Decision violates the APA.

IV. CONCLUSION

For the foregoing reasons, Petitioner respectfully requests that the Director grant Director Review, vacate the discretionary denial (Paper 10), and refer the Petition for a merits institution determination in the normal course.

Dated January 9, 2026,

Respectfully submitted,
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CERTIFICATE OF SERVICE UNDER 37 CFR § 42.6(e)(4)

The undersigned hereby certifies that a copy of the foregoing Petitioner's Request for Director Review of Decision Denying Institution, is being served on January 9, 2026, via email directed to the following counsel of record for the Patent Owner:

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