

Filed on behalf of: Eli Lilly & Co.

Entered: January 16, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BPI LABS, LLC,
Petitioner,

v.

ELI LILLY & COMPANY,
Patent Owner.

IPR2025-01346
Patent No. 9,474,780

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

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Patent Owner Eli Lilly & Co. (“Lilly”) respectfully submits this Response to Petitioner BPI Labs, LLC’s (“Petitioner” or “BPI”) Request for Director Review (Paper 11, “Request”) of the decision denying institution (Paper 10, “Denial”). Like Empower—whose materially similar request was denied this week—BPI identifies no meaningful legal or factual basis for the extraordinary intervention it seeks. *See Empower Clinic Servs., LLC v. Eli Lilly & Co.*, IPR2025-01024, Paper 18 (P.T.A.B. Jan. 12, 2026) (“Empower IPR”). Instead, BPI recycles arguments the Director already rejected, falsely accuses Lilly of hiding references it cited in the specification, and seeks to create special rules for patents in the pharmaceutical industry. BPI’s APA challenge fares no better. The Director’s discretionary denial does not rest on any binding, substantive rule requiring notice-and-comment. And because the AIA commits institution to the Director’s unreviewable discretion, 35 U.S.C. § 314(d); 5 U.S.C. § 701(a), the APA does not require more explanation than was provided. On the record here—reflecting strong settled expectations in a nearly decade-old patent, substantial investment and commercialization, and no material examination error—the denial was a proper exercise of discretion and fully consistent with the Empower IPR. For these reasons, and to ensure consistent treatment of materially similar records, BPI’s Request should be denied.

I. Legal Standards

Requests for Director Review are governed by 37 C.F.R. § 42.75 and “shall be limited to decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” USPTO, Director Review Process § 2.B.

Discretionary denial is committed to the Director’s judgment and is based on a holistic assessment of the record. USPTO, Memorandum on Interim Processes for PTAB Workload Management (Mar. 26, 2025) (“Interim Processes Memo”). Applying that framework, BPI’s Request identifies no abuse of discretion, no erroneous factual or legal determinations, and no important issue of law or policy warranting intervention. To the contrary, the record reflects a proper exercise of discretion under § 314(a), grounded in Lilly’s strong settled expectations and the absence of any material examination error, as the Director already determined in the Empower IPR. Empower IPR, Papers 15, 18.

II. Discretionary Denial of Institution Was Proper

A. Lilly's Settled Expectations Are Strong And Well-Supported

Lilly has strong settled expectations in the nearly decade-old '780 patent, as the Director¹ correctly found in discretionarily denying Empower's Petition. Empower IPR, Paper 15 at 2. Like Empower, BPI argues that the Director erred by relying on Lilly's enormous investment in developing the claimed invention, which included more than 80 clinical trials involving tirzepatide, an embodiment of the claimed invention. According to BPI, these scores of trials do not support Lilly's settled expectations in the '780 patent because Lilly discovered additional patentable inventions along the way. Request 4-5. The Director denied Director Review in the Empower IPR when faced with these same arguments. Empower IPR, Paper 18.

Contrary to BPI's assertion, there is a clear "nexus" between Lilly's over 80 clinical trials and the claimed invention: *each* of those trials evaluated tirzepatide, which unequivocally embodies the claimed invention. This is precisely the type of investment the settled expectations analysis seeks to protect: it evaluates both how long the patent has been in force (here, nine years) and the patentee's post-issuance reliance on and investment in the patent. *See* Empower IPR, Paper 15 at 2; *Amgen*

¹ While the Empower IPR decision was signed by Deputy Director Stewart, we refer to her herein as Director, since the decision was made on behalf of the Director.

Inc. v. Bristol-Myers Squibb Co., IPR2025-00601, -00602, -00603, Paper 9 at 2-3 (P.T.A.B. July 24, 2025) (“[A]n extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations.”).

Lilly's investments based on the nearly decade-old '780 patent include not only over 80 clinical trials evaluating tirzepatide, but also substantial additional investments in manufacturing capacity (committing over \$50 billion in infrastructure investments for research and manufacturing in the U.S., creating thousands of U.S. jobs), regulatory approvals for Mounjaro[®] and Zepbound[®], and product launches, all anchored to the patented invention. Paper 6 at 7. And Lilly continues to invest in tirzepatide today, investing in its safety and efficacy for treating additional diseases and disorders. Exs. 2049, 2050. These facts confirm robust and continued reliance and investment in the '780 patent and strong settled expectations.

That these investments occurred after the patent issued supports Lilly, not BPI. By its very nature, settled expectations focuses on investments made *after* the challenged patent issued. That Lilly also made additional inventions as a result of its continued investment in and development of the '780 patent, and its claimed compounds, does not detract from Lilly's strong settled expectations. To the contrary, it was the '780 patent that paved the way for those subsequent inventions.

Moreover, BPI's argument that the Director should apply different standards to Orange Book patents is unsupported. Request 5-6. BPI has known or should have known of the '780 patent for many years, including based on Lilly's publicity and the Orange Book listing, and nothing in the Hatch-Waxman statutory framework prohibited BPI from challenging the '780 patent sooner. BPI's delay in seeking PTAB review is precisely the kind of delay that weighs against institution.²

Finally, BPI's argument about drug pricing is irrelevant and meritless. Request 6. Lilly is working hand in hand with the Administration to expand access and lower out-of-pocket costs for tirzepatide medicines. Regardless, the price of Lilly's patented drugs does nothing to overcome BPI's failure to establish Office error or articulate compelling grounds for Director Review.

B. BPI Has Failed To Identify Any Material Error

BPI argues that it "has identified material errors similar to those identified in" the Empower IPR. Request 2. That dooms its cause, for the Director correctly found

² BPI's argument concerning Orange Book patent listings is a strawman. Request 5, n.1. Lilly never argued that Orange Book listing "establish[ed] nexus." *Id.* Rather, Lilly cited the Orange Book to show that BPI has been on notice of the patent for many years, which BPI does not dispute. Thus, BPI's argument that Orange Book listings are "routine, unilateral assertion[s]," even if true, is irrelevant.

Empower's "similar" assertions unpersuasive. Empower IPR, Paper 15 at 3; *see id.*, Paper 18. For the same reasons, BPI's assertions of examiner error—which BPI's Petition never raised—are unpersuasive and should be rejected. Taking the same tack as Empower, BPI accuses Lilly of intentionally hiding prior art—the Alsina-Fernandez reference. Request 3. That is demonstrably false. Contrary to BPI's assertion that Alsina-Fernandez was "the proverbial needle in a haystack," Request 3, Lilly prominently cited Alsina-Fernandez twice in the '780 patent specification—including in the patent's very first column—and explained that Alsina-Fernandez disclosed "[c]ertain GIP analogs" with "both GIP and GLP-1 activity." Ex. 1001 ('780 patent), 1:55-57, 20:63-64. This is the opposite of hiding a reference.

Further, the record shows that the Examiner considered Alsina-Fernandez and its sequences, which were identified in the Examiner's Search Results. The Search Results identify Alsina-Fernandez and its SEQ ID NOs:1-5 (which includes BPI's alleged lead compound) in its *first four pages*. Ex. 2088, 1-4 (Search Results dated July 14, 2016, <https://data.uspto.gov/patent-file-wrapper/search/details/14987791/documents>). Between the many disclosures in the specification and the Search Results, there is no question the Examiner considered the relevant disclosures before properly allowing the claims.

C. BPI Cites No Authority Warranting Reconsideration

BPI identifies no authority supporting reversal on these facts. To Lilly's knowledge, the Director has overturned a discretionary denial only once since the start of the bifurcated discretionary denial USPTO procedures, and this case is nothing like that one. In *Arm Ltd. v. Daedalus Prime LLC*, institution was discretionarily denied based on a parallel litigation, which subsequently settled, creating a major change in circumstance. IPR2025-00207, Paper 14 at 2 (P.T.A.B. Aug. 6, 2025). Moreover, in that case, the "[p]etitioner explain[ed], the Board already ha[d] determined that 'substantially identical claims' in a related patent ... [we]re unpatentable." *Id.* at 3.

Here, there is no comparable change in circumstance, no new controlling legal development, no abuse of discretion, and no erroneous findings of fact or conclusions of law. Instead, this case closely resembles recent denials of Director Review, including in the Empower IPR involving a materially identical record and petitioner arguments. *See* Empower IPR, Paper 18; *see also, e.g., Murata Mfg. Co. v. Georgia Tech Rsch. Corp.*, IPR2025-00383, -00384, Paper 17 at 2 (P.T.A.B. Oct. 15, 2025). The Request, at bottom, reargues points already considered and rejected. In view of the Director's recent decision denying Director Review in the Empower IPR and BPI's acknowledgement that its arguments are substantially identical to

Empower's arguments, "consistency" between these IPRs warrants denial here too. Request 7; Empower IPR, Paper 18.

D. The Discretionary Denial Does Not Violate The APA

Petitioner argues that the discretionary denial violates the APA. It does not. Because the discretionary factors underlying the discretionary denial were not established by substantive rule, the APA does not require notice-and-comment. And because the Director has unreviewable discretion over institution decisions, the APA does not require further explanation for the denial itself.

1. The Denial Did Not Rest On Any Substantive Rule That Would Require Notice-And-Comment

In two recent memos, the Director provided instructions for institution decisions. The Interim Processes Memo described how the Director's discretion over institution will be exercised, including a non-exhaustive list of considerations. Interim Processes Memo at 2-3. The Director Institution Memo introduced procedures for institution decisions, including summary denials. USPTO Memorandum on Director Institution of AIA Trial Proceedings at 1-2 (Oct. 17, 2025). Petitioner contends that the denial decision was based on these instructions, and that the instructions were improperly promulgated without notice-and-comment.

It is true that, before adopting certain rules, agencies must notify the public and allow comments on the proposal. 5 U.S.C. § 553(b)-(c). But only "substantive" (or "legislative") rules require notice-and-comment. *Lincoln v. Vigil*, 508 U.S. 182,

196 (1993). The requirement “does not apply” to “general statements of policy.” 5 U.S.C. § 553(b)(4)(A). The Director’s instructions are not substantive rules, but general policy statements. So they did not require notice-and-comment.

Substantive rules “alter the landscape of individual rights and obligations, binding parties with the force and effect of law.” *Xi'an Metals & Mins. Imp. & Exp. Co. v. United States*, 50 F.4th 98, 106 (Fed. Cir. 2022) (citation omitted). To determine what qualifies as a substantive rule, courts focus on: (1) whether the rule “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); and (2) whether the rule “leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the announced policy in an individual case,” *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987) (citation modified).

The Director’s instructions neither affect individual rights nor bind the agency. Indeed, the district court in *Apple Inc. v. Vidal*, 2024 WL 1382465, *8-13 (N.D. Cal. Mar. 31, 2024), *appeal docketed*, No. 24-1864 (Fed. Cir. May 15, 2024), already reached the same conclusion with respect to similar instructions. That decision is correct and the same result is warranted here.

An institution denial alters no individual rights or obligations. Petitioner has no right to institution—the Director has complete prerogative over the decision. 35 U.S.C. § 314(d); *United States v. Arthrex, Inc.*, 594 U.S. 1, 8-9 (2021). And

institution has no impact at all on the rights actually at issue in IPR: the patent owner's rights of control and the petitioner's freedom to operate. Unlike a final decision from PTAB, institution denial does not cancel or confirm patent claims. *See* 35 U.S.C. §§ 315(e), 318(a). Nor does denial preclude the parties from seeking relief through other means, such as reexamination or a lawsuit.³ Consequently, denial does not implicate any individual rights. *Vidal*, 2024 WL 1382465, at *9. The Director's instructions therefore did not require notice-and-comment.

The Director's instructions also leave significant discretion for individual institution decisions. For starters, the instructions do not bind the Director, who can modify the institution factors and decide whether and how to apply them. *See Vidal*, 2024 WL 1382465, at *12 (collecting examples). Nor do the instructions preordain institution decisions themselves. The instructions are not outcome-determinative; they do not require the grant or denial of institution in any particular case. *Id.* at *12-13. Instead, they set forth a non-exhaustive set of factors, reserving space for "[a]ny other considerations bearing on the Director's discretion." Interim Processes Memo at 2-3. That preserves "genuine discretion to evaluate all facts and

³ An adversarial suit is available if Petitioner has a concrete interest in challenging the patent. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-37 (2007). And *ex parte* reexamination is available "at any time." 35 U.S.C. § 302.

circumstances relevant to the institution.” *Vidal*, 2024 WL 1382465, at *13. For this reason, too, they are not substantive rules requiring notice-and-comment. *Id.*

All of that reinforces that the Director’s instructions are, in fact, just general policy statements. Such statements merely “advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.” *Lincoln*, 508 U.S. at 197 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979)); see *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). That is exactly what the Director’s instructions do here. The instructions in the memos “advise the public prospectively of the manner in which [USPTO] proposes to exercise [the] discretionary [institution] power.” *Lincoln*, 508 U.S. at 197 (citation omitted). As general policy statements, they required no notice or comment.

Petitioner’s arguments to the contrary lack merit. Petitioner completely fails to address the “critical factor” of whether the rule is binding on the agency, *Mada-Luna*, 813 F.2d at 1013. And the arguments Petitioner does raise fail.

Petitioner repeatedly invokes the Federal Circuit’s decision in *Apple v. Vidal*, which held Apple had standing to challenge similar Director instructions on notice-and-comment grounds because of their “predictable effect” of “more denials of institution than might otherwise occur.” *Apple Inc. v. Vidal*, 63 F.4th 1, 16-17 (Fed. Cir. 2023). Remarkably, Petitioner fails to mention that, on remand, the district court determined the instructions were general agency policy statements and *not*

substantive rules. The district court distinguished “the threshold analysis of standing” from “the merits of the APA claim.” *Vidal*, 2024 WL 1382465, at *9 & n.5. That makes sense. That an agency rule results in an “injury in fact,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992), does not mean it also “alter[s] the landscape of individual rights and obligations,” *Xi'an Metals*, 50 F.4th at 106 (citation omitted). Parties regularly have standing to challenge non-substantive rules even though, all agree, such rules are not subject to notice-and-comment. *E.g., Kisor v. Wilkie*, 588 U.S. 558, 583-84 (2019). As the district court in *Vidal* correctly held, injury in fact does not transform a general policy statement into a substantive rule.

Picking up on the distinct injury-in-fact requirement, Petitioner predicts an “increased chance of denial” under the instructions, and says those changed odds make the instructions a substantive rule. Request 12. Even assuming Petitioner’s forecast is true, it does not speak to the controlling question. Without changes to legal rights or obligations, practical consequences for the parties do not render a rule substantive. *See, e.g., Lincoln*, 508 U.S. at 196-98 (memo “discontinuing [a] Program and reallocating its resources” was “surely” no substantive rule because it did not alter legal standards, even though it “affect[ed] the availability of services”); *Mada-Luna*, 813 F.2d at 1016 (“expressly reject[ing] the argument that ... courts should look to the ‘substantial impact’ of the rule” to determine whether it required notice-and-comment) (citation modified); *Nat’l Mining Ass’n*, 758 F.3d at 250, 252

(deeming EPA guidelines not to be a substantive rule even though they “may signal likely future permit denials”).⁴ Whether the Director’s instructions are substantive rules does not turn on what they portend for rates of institution denials.

Petitioner also relies on the AIA’s structure. The Director must adopt certain rules governing IPR by “prescrib[ing] regulations,” including by “setting forth the standards for the showing of sufficient grounds to institute a review.” 35 U.S.C. § 316(a). According to Petitioner, “Congress’s use of the term ‘regulations’ generally denotes” substantive rules “issued after notice and comment.” Request 13-14 (citation omitted). Petitioner reasons that (i) because the Director’s instructions bear on IPR review factors, they must be regulations, and (ii) because they are regulations, they must be substantive rules. That is wrong on both counts.

First, Director instructions bearing on institution decisions are not necessarily “regulations” under 35 U.S.C. § 316(a)(2). Regulations are not the only way to

⁴ Petitioner’s own authorities only confirm that conclusion. *See Chestek*, 92 F.4th at 1109 (explaining that labeling any rule “that impacts outcomes ... as substantive” would “obliterat[e] ... the distinction” of substantive rules) (citation omitted); *Am. Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1046-47 (D.C. Cir. 1987) (parole guidelines were a substantive rule because of the “substantial effect *on ultimate parole decisions*,” not just any “‘substantial impact’ on parties”) (emphasis added).

explain the factors and process involved in that wholly discretionary decision. In fact, the AIA separately requires the Director to “provid[e] policy direction and management supervision for the Office.” *Id.* § 3(a)(2)(A). This is precisely what these instructions did. Second, even if the instructions are labeled “regulations,” that does not make them substantive rules. It is well-settled that statutory references to “regulations” preserve the “exceptions to notice-and-comment rulemaking contained within § 553(b).” *Chestek*, 92 F.4th at 1110.⁵

2. The Denial Did Not Require A Full And Reasoned Explanation

Petitioner also argues that the APA requires more explanation for the institution denial so that it can be evaluated by “a reviewing court.” Request 14-15. But the AIA precludes courts from reviewing the reasons for institution denial, and Petitioner does not allege—much less demonstrate—other statutory or constitutional deficiencies requiring judicial review of this one.

Under the APA, there is no judicial review where “statutes preclude” it, or where “agency action is committed to agency discretion by law.” 5 U.S.C. § 701(a). The AIA does both: the “Director shall determine whether to institute an inter partes

⁵ *United States Telecom Association v. FCC* did not hold otherwise. It just explained that regulations defining legal duties are substantive rules. 400 F.3d 29, 38 (D.C. Cir. 2005). As shown above, the Director’s instructions alter no legal duties.

review,” and that determination “shall be final and nonappealable.” 35 U.S.C. § 314(b), (d); *see Vidal*, 63 F.4th at 7. That unreviewability does not “turn[] on” any explanation for institution’s denial. *Vidal*, 63 F.4th at 13. And “[i]f the decision is unreviewable, then there is no need for explanations.” *Lalani v. Perryman*, 105 F.3d 334, 338 (7th Cir. 1997). In short, there will be no “reviewing court,” Request 15, that needs more explanation to evaluate this denial.

Petitioner’s supporting citations are inapposite. Two note the need for a reasoned explanation of final, post-institution IPR merits decisions, which are reviewable—not institution decisions themselves. *See Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 988-89, 992 (Fed. Cir. 2017); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1313-14, 1322 (Fed. Cir. 2016). And the other two suggest that notwithstanding § 314(d), judicial review may be available when an agency engages in “‘shenanigans’ [that] exceed[] its statutory bounds,” or in “appeals that implicate constitutional questions.” Request 15 (citations omitted). Neither kind of exception is implicated here, and Petitioner does not argue otherwise. So, the Director’s unreviewable discretion over institution decisions remains in full force, and the APA requires no further explanation for the denial of this petition.

III. Conclusion

For the reasons above, the Board should deny BPI’s request for Director Review.

Respectfully submitted,

Dated: January 16, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 16th day of January, 2026, a true and correct copy of the foregoing **Patent Owner's Authorized Response to Petitioner's Director Review Request** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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