

Filed on behalf of: Eli Lilly & Co.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMPOWER CLINIC SERVICES, L.L.C.
(D/B/A EMPOWER PHARMACY),
Petitioner,

v.

ELI LILLY & CO.,
Patent Owner.

IPR2025-01024
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 Empower Clinic Services, L.L.C.’s (“Petitioner” or “Empower”) Request for Director Review (Paper 16, “Request”) of the decision denying institution (Paper 15, “Denial”). Empower identifies no meaningful legal or factual basis for the extraordinary intervention it seeks. Instead, Empower recycles arguments the Director¹ already considered and rejected, introduces new arguments waived by omission, and makes a host of hyperbolic and false accusations, including that Lilly intentionally hid references it cited in the specification, that Orange Book listings should be ignored as “routine,” and that Lilly’s drug prices are somehow relevant to institution of a meritless petition. Discretionary denial was a proper exercise of the Director’s authority under 35 U.S.C. § 314(a), given Lilly’s strong settled expectations in a nearly decade-old patent, Lilly’s substantial investment and commercialization, and lack of Examiner error. Empower’s Request should be denied.

I. Legal Standard

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

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

law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” USPTO, Director Review Process (“Director Review Process”) § 2.B, <https://www.uspto.gov/patents/ptab/decisions/director-review-process>.

Discretionary denial is committed to the Director’s judgment and is based on a holistic assessment of the record, including settled expectations and Office efficiency and workload management. USPTO, Memorandum on Interim Processes for PTAB Workload Management (Mar. 26, 2025), <https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>; *see also Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) (establishing that “the [Patent Office]’s decision to deny a petition is a matter committed to the Patent Office’s discretion”) (original alteration) (citing *Cuozzo Speed Techs., LLC v. Com. for Intell. Prop.*, 579 U.S. 261, 272-73 (2016)), *cert denied*, 142 S. Ct. 874 (2022); *Murata Mfg. Co. v. Ga. Tech Rsch. Corp.*, IPR2025-00383, Paper 17 at 2-3 (P.T.A.B. Oct. 15, 2025) (denying Director Review because the decision denied institution based on a holistic assessment, including patent owner’s strong settled expectations and petitioner’s delay, finding the request “not persuasive”).

Applying that framework, Empower’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.

II. Discretionary Denial of Institution Was Proper

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

The Director correctly found that Lilly has strong settled expectations in the nearly decade-old '780 patent. Denial 2. Empower 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 Empower, 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 2-3. That is wrong and completely misses the point.

Contrary to Empower's suggestion, there is a clear "nexus" between Lilly's 83 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, e.g., Dabico Airport Sols. Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 at 2-3 (P.T.A.B. June 18, 2025) (explaining that "the longer the patent has been in force, the more settled expectations should

be”); *Intel Corp. v. Proxense LLC*, IPR2025-00327, -00328, -00329, Paper 12 at 2-3 (P.T.A.B. June 26, 2025) (whether a patent was “commercialized ... or otherwise applied in a petitioner’s particular technology space” after issuance is relevant to a claim of settled expectations); *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, -00602, -00603, Paper 9 at 2-3 (P.T.A.B. July 24, 2025) (“an extraordinary amount of investment, time, and resources dedicated to research, development, trials, and regulatory approval correlates to settled expectations”); *see also* Denial 2.

In the nine-plus years since the ’780 patent issued, Lilly has invested an extraordinary amount of time, money, and resources in the claimed invention. Paper 6 (“DD Brief”) 15-16. That investment includes not only at least 83 clinical trials evaluating tirzepatide, but also substantial additional investments in manufacturing capacity (committing over \$50 billion in infrastructure investments for drug research and manufacture 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. And Lilly continues to invest in tirzepatide today, investigating its safety and efficacy for treating additional diseases and disorders, including heart failure with preserved ejection fraction, metabolic dysfunction-associated steatohepatitis, cardiovascular risk reduction, chronic kidney disease, plaque psoriasis, and psoriatic arthritis. Exs. 2049, 2050. These facts

confirm robust and continued reliance and investment in the '780 patent and strong settled expectations.

The fact that these investments occurred after the patent issued supports Lilly, not Empower. 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.

The '780 patent is over nine years old, and Lilly's substantial and ongoing investments and the commercialization of products embodying the patented invention (Mounjaro® and Zepbound®) fully support the Denial. Empower does not dispute that it has known or should have known of the '780 patent for many years, including based on the Orange Book listing, yet waited nearly a decade to seek PTAB review—precisely the kind of delay that weighs against institution.

Finally, Empower's argument concerning Orange Book patent listings is a strawman. Request 3-4. Lilly never argued that Orange Book listing, in and of itself, “automatically immunizes a patent from further Office review.” *Id.* 3. Rather, Lilly cited the Orange Book merely to show that Empower has been on notice of the patent

for many years, which Empower *does not dispute*. Thus, Empower's argument that Orange Book listings are "routine," even if true, is irrelevant.

B. Empower Has Failed To Identify Any Material Error

The Director also correctly found Empower's assertions of examination error unpersuasive. Denial 3. Empower's Request once again accuses Lilly of intentionally hiding prior art—the Alsina-Fernandez reference—and "invit[ing] material examiner error." Request 4. That is demonstrably false and Empower ignores ample evidence to the contrary. Lilly cited Alsina-Fernandez twice in the '780 patent specification, including in the very first column of the patent, 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 (all of which are within the scope of Empower's "lead compound") in its *first four pages*.² Ex. 2088, 1-4

² Empower complains that the Search Results are 202 pages long and include 105 search reports. Request 4. It is unclear how Empower calculated its alleged "105

(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. Empower's arguments to the contrary are merely an attempt to distract from these established facts.

Undeterred, Empower's Request pivots to new theories centered on the Examiner's Search Results, which Empower conspicuously *omitted* from its version of the prosecution history (Ex. 1004), and Lilly's participation in the Patent Prosecution Highway (PPH). Empower is wrong on both counts.³

Empower advances a convoluted and confused argument about the Search Results, which is apparently designed to suggest that somehow the Examiner did not

search reports," but, regardless, the relevant Alsina-Fernandez disclosure was produced in the ***very first*** search report in the first four pages of the document.

³ Not only do Empower's arguments fail on the merits, they are also waived because Empower never raised them until its sur-reply opposing Discretionary Denial and/or Request for Director Review. *See* Director Review Process § 3.E; *Garrido v. Holt*, 547 F. App'x 974, 979 (Fed. Cir. 2013) (finding the PTAB did not err in declining to address new arguments not properly raised on appeal because they were raised for the first time in a request for rehearing and contrary to previous positions).

search for the right thing in examining Lilly's claims. Empower's premise appears to be that the claimed sequence was never searched, and that the minutiae of the Search Results somehow prove this. Request 4-6.

Empower's premise, and its overall assertion of Examiner error, are demonstrably false. By the time the Scientific and Technical Information Center (STIC) was asked to perform the searches that Empower now flyspecks in order to disparage the Examiner, *the Examiner had already searched for the claimed sequence*. Ex. 2088, 1 (noting the Examiner "submitted an ABSS search for the [claimed] sequence"). The STIC's search was a *second, broader search* requested by the Examiner. *Id.* Having already searched the full sequence, the Examiner went even farther and requested a search for a portion of the full sequence. *Id.* The "hits" in the STIC's search therefore reflect the matches that were found to the sequence fragments that the STIC searched for, rather than matches for the full claimed sequence. *Id.*, 2. The Examiner surely understood this fact given that she had searched for matches against the full claimed sequence herself and then asked the STIC to do a subsequent broader search. *See id.*, 1; *id.*, 2 (identifying the STIC's searches). At bottom, Empower attempts to seize on immaterial presentation quirks in the Search Results to manufacture error where none exists, in an effort to distract from the dispositive point: the very prior-art disclosure it now labels "new" was squarely before the Examiner during prosecution—including in the very Search

Results to which Empower devotes so much attention. There was no material Office error, and the Director properly exercised discretion in denying the Petition.

Finally, Empower's complaint that the Examiner issued claims without a prior rejection, and that the participation in the Patent Prosecution Highway ("PPH") somehow tainted patentability, is legally untenable. Request 6. Claims meeting patentability requirements may be allowed without rejection, and mere participation in the PPH, an established Office program, surely cannot be a basis demonstrating Examiner error. Further, while the Examiner issued the claims without rejection, she did so with detailed Reasons for Allowance, explaining her reasoning and why hindsight would have been necessary to arrive at the claimed inventions from the prior art. Ex. 1004, 27-30. In sum, Empower's Request does nothing to undermine the Director's correct conclusion that Empower failed to show any Office error—let alone error material to patentability. DD Brief 22-36; Denial 3.

C. Empower Cites No Authority Warranting Reversal

Empower 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. *See, e.g., Murata*, IPR2025-00383, -00384, Paper 17 at 2 (upholding discretionary denial “based on a holistic assessment of all the evidence and arguments presented, including Patent Owner’s strong settled expectations”). The Request, at bottom, reargues points already considered and rejected, and raises new arguments that were not properly raised below. Neither is a basis for Director Review.

D. Empower’s Drug Pricing Arguments Do Not Favor Institution

Empower’s arguments about drug pricing are both irrelevant and meritless. Lilly has long been working with the Administration to expand access and lower out-of-pocket costs for tirzepatide medicines, culminating in agreements announced in the Oval Office at a ceremony attended by, among others, the Secretary of Commerce. Press Release, Eli Lilly & Co., Lilly and U.S. Government Agree to Expand Access to Obesity Medicines to Millions of Americans (Nov. 6, 2025), <https://investor.lilly.com/news-releases/news-release-details/lilly-and-us->

government-agree-expand-access-obesity-medicines. The President himself has praised Lilly for its efforts in this regard and credited Lilly and its collaboration with the Administration for this effort. The Hill, Happening Now: Trump Makes Announcement On Weight Loss Drug Prices, at 01:17, 04:13, 12:01, 15:15, 18:10, 32:10 (YouTube, streamed Nov. 6, 2025), <https://www.youtube.com/watch?v=4Mv0CGGt2Yo>. Regardless, the price of Lilly's patented drugs does nothing to overcome Empower's utter failure to establish material Office error or articulate any compelling grounds for Director Review. Director Review is not a policy forum for drug pricing, and Empower's assertions are unsupported, contrary to Lilly's public record of action, and do not establish a basis for Director Review.

III. Conclusion

For the reasons above, the Board should deny Empower's request for Director Review.

Respectfully submitted,

Dated: November 20, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 20th day of November, 2025, 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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