

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.

Case IPR2025-01024
Patent US 9,474,780

EMPOWER PHARMACY'S REQUEST FOR DIRECTOR
REVIEW OF THE DISCRETIONARY-DENIAL DECISION

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I. INTRODUCTION

Petitioner Empower Pharmacy requests Director review of the acting Director’s discretionary-denial decision (Paper 15, DDD). The issues Petitioner raised—the Office’s clear error in issuing this patent covering common prescription tirzepatide (including MOUNJARO for diabetes, ZEPBOUND for weight loss)—are simply too important to be decided by anyone other than the Executive branch officer responsible for patent quality himself.

The DDD specifically denied institution based on “settled expectations,” but credits evidence that has little nexus to the challenged patent. Indeed, Patent Owner Lilly relies on clinical trials it used to obtain recent, unchallenged patents grants. But Lilly cannot immunize the challenged patent based on investments in later, unrelated patents that are not themselves entitled to settled expectations, and Lilly’s attempt to do so should be reconsidered and rejected.

As a result of the DDD, the U.S. Treasury and American taxpayers could continue to be saddled with needlessly high prescription costs because of correctable Office error—an outcome inconsistent with, if not directly contrary to, Administration policy to optimize patent policy to lower the needlessly high costs of tirzepatide prescriptions. The petition materials made an unusually strong showing of error that even includes an explanation of how and why the examiner went astray. This is a paradigmatic case of a patent requiring the “strong medicine”

of further Office review. Director review should be granted and trial instituted to remedy this clear Office error.

II. LILLY’S ILLUSORY “SETTLED EXPECTATIONS”

As the proponent of its settled-expectations argument, Lilly had the burden to establish its expectations were truly settled. Yet, the Lilly showing that the DDD adopted lacks nexus to the challenged patent. DDD, 2 (“In particular, Patent Owner has conducted 83 clinical trials involving tirzepatide.”) Indeed, as Empower’s opposition showed (Paper 11, DDO, at 5-6, 51-54, 59-62), Lilly made essentially no effort to tie the challenged patent to its purported investments and trials, because such nexus was facially lacking. In fact, the “83 clinical trials” ***undermine*** Lilly’s purported showing because most of these trials go to ***later*** patents that are not related by priority to the challenged ’780 patent. DDO, 59-62. Despite this fatal gap in its purported showing, Lilly made no effort in its reply (Paper 12, DDRep) to show nexus—again—because it cannot. Lilly’s silence on this most salient point of decision speaks volumes; indeed, it is dispositive.

The DDD overlooked the import of the lack of such nexus. Lilly cannot manufacture settled expectations for the challenged patent based on investments for ***different, unrelated patents*** that issued so recently (June 2022-July 2025) that they are not entitled to settled-expectation protections. DDO, at 61; EX2044; EX1080; EX1081. Lilly’s improper allocation to the challenged patent of investments in later-

claimed inventions improperly double-counts those investments and paradoxically seeks to derive settled-expectation immunity from later, unrelated patents that are themselves too new for settled expectations. Lilly's argument would allow evergreening patentees to play a shell game that vitiates the Administration's settled-expectations doctrine. Thus, Lilly's improper argument not only defies logic and law, but also contradicts the Administration's own policies.

Similarly, Lilly urged the acting Director to rely on an Orange Book listing for the challenged patent; yet, as the DDO explained, an Orange Book listing is just a routine, unilateral patentee assertion required by statute. DDO, 51-54; *accord Teva Branded Pharm. v. Amneal Pharms.*, 124 F.4th 898, 904-05 (Fed. Cir. 2024) ("When an [new drug application] holder that owns a patent-submits an NDA, it must submit information on 'the patent number and expiration date of each patent'...."), *citing* 21 U.S.C. 355(b)(1)(A)(viii). Importantly, "[t]he FDA does not police this process, as it has long taken the position that it lacks patent-law expertise and thus cannot determine whether the patents that a patent owner lists in the Orange Book are properly included." *Teva*, 124 F.4th at 906. Once again, accepting Lilly's argument that a routine, self-serving, untested Orange Book listing automatically immunizes a patent from further Office review turns the Administration's settled-expectations policy on its head, because it allows pharmaceutical patentees to manufacture their own immunity simply by listing the patent in the Orange Book. Lilly's argument

enables pharmaceutical patentees to unilaterally undermine the Administration's commitment to strong patents and improperly drive up prescription costs for the U.S. Treasury and for American taxpayers. The Office cannot rely on Orange-Book listing as a certification that a patent is somehow valid because the FDA has expressly rejected any responsibility for such certification. The FDA is not a forum for identifying and curing Office error: addressing its own errors is the Office's duty. Empower respectfully urges the Director to resist Lilly's efforts to neuter Executive power and undercut Administration goals.

III. LILLY KNEW OF THE OFFICE'S UNUSUALLY MANIFEST ERROR, BUT CHOSE TO REMAIN SILENT

A patentee that invites material examiner error and remains silent in the face of clear known error cannot possibly have settled expectations that its patent was born strong, which makes this case extraordinary in several ways. As the petition (Paper 2, Pet.) established, Lilly did not provide the closest prior art (Lilly's own publication, EX1007) to the examiner, and the examiner never cited it. Instead, the examiner applied less-relevant art, and then found it was overcome because it lacked a glutamine (Gln or Q) at position 24 (a criticism inapplicable to EX1007). Pet., 7-8. When Lilly argued to the acting Director that EX1007 was mentioned in a 202-page STIC sequence-search result (one of 105 search reports), the reason why the examiner went astray became clear: the STIC librarian had ignored the critical part of the search that the examiner had requested and thus failed to identify the critical

sequence overlap precisely where the examiner was most interested. Paper 14 (DD Surreply, DDS), 2.

Importantly, the examiner failed to spot STIC's error. The figure below,

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CN 1: PN: WO2011119657 SEQID: 1 claimed protein
CI MAN
SQL 44

SEQ 1 YXEGTFTSDY SLDKIAQR AXVQWLIAXK GKKQEWKHQI TQXX
      =====
HITS AT: 4-11, 14-19
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which is an entry on page 4 of Lilly's EX2088 (STIC search report), shows the sequence of the reference now being applied (EX1007), but which the examiner missed. Green annotations added to the figure clearly show not only the many matches (hits) that STIC inexplicably failed to identify (i.e., they are missing the equal sign underneath that indicates a hit), but also show STIC specifically overlooked the matching glutamine (Q) at position 24 (in the third block of missed hits) that the examiner considered key to her reasons for allowance. This error could not be more glaring.

Indeed, not only is the examiner's error manifest in the record but, unusually, the reason the examiner went astray is also manifest in the record—STIC's botched search results buried and mislabeled the closest sequence. The Director has emphasized the need for better search tools. J.C. Squires, *Questions from Senator*

Grassley,¹ Responses (“Squires Responses”) 5 (“A thorough and comprehensive prior art search is the foundation of every patent examination and the foundation of quality and confidence in the patent system.”) and 6 (advocating “the use of LLMs and other AI-assisted tools to better manage the complicated and onerous task of searching for and identifying the most relevant prior art.”). Here, either the search tools or the users failed because STIC and the examiner failed to identify the best, most relevant hits.

Compounding this error, the examiner allowed the claims without a rejection, apparently based on a European search report (EX1005) and opinion (EX1006) that also missed the essential EX1007 reference. Pet., 7. The examiner outsourced her examination to a comparably deficient foreign patent office via the Patent Prosecution Highway (PPH). EX1004, 48-49. Indeed, this examination is a posterchild for why slowing PPH applications is necessary:² under the pre-January 20, 2017 regime, PPH practice had evolved into little or no examination at all for many applications, like this one.

¹ Available at https://www.judiciary.senate.gov/imo/media/doc/2025-05-21_qfrresponses_squires.pdf.

² Update to Patent Prosecution Highway Docketing (USPTO 2025), available at <https://content.govdelivery.com/accounts/USPTO/bulletins/3f90f61>.

What is also manifest is that Lilly knew the examiner had materially erred—because Lilly knew its own prior-art publication showed the better sequence—and chose to remain silent. Lilly’s approach turns applicant candor on its head and thus fatally undermines this Administration’s goal of producing born-strong patents. Squires Responses 3.a. (“I believe it is to the benefit of all stakeholders if prior art is identified and applied at the earliest stage of examination **or post issuance**, as we benefit as a society from patents ‘born strong,’ beginning with the original patent grant.”) (emphasis added). Strong prosecution breeds broad respect for patent grants, but leaving known, clear, material prosecution errors uncorrected subverts the integrity of the patent system and any presumption of validity.

Given the materiality and unmistakability of the Office’s error in allowing the challenged claims, discretionary denial in this case needlessly imposes higher pharmaceutical costs on the U.S. Treasury and on American taxpayers and patients.

IV. UNSETTLED ADMINISTRATION POLICIES

“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.” E.O. 14273, *Lowering Drug Prices by Once Again Putting Americans First*, 90 Fed. Reg. 16441 (2025). Lilly instead would have this Administration:

- misallocate investment in **other** patents—including patents with no settled

expectations—to challenged patents;

- credit Orange Book listings—which are untested and utterly routine for pharmaceuticals—in all cases as demonstrating settled expectations in pharmaceutical patents; and
- preserve materially-defective patents to pharmaceutical companies (foreign and domestic), even when the patentees know of the defect and remain silent before the Patent Office.

Far from optimizing U.S. patent protections, Lilly’s goals make a mockery of the Patent Office’s commitments to born-strong patents and ***legitimate*** settled expectations. Worse yet, Lilly’s goals materially contradict an explicit Administration goal of optimizing Federal intellectual property protections to provide access to prescription drugs at lower costs to American patients and taxpayers. E.O. 14273.

The Commerce Department, and the Patent Office operating within it, share an integral role in implementing the Administration’s policies embodied by E.O. 14273. *See A. Bettelheim, Exclusive: Lutnick says Trump will force drugmakers to lower prices, The Axios Show (Sept. 12, 2025) (Secretary Lutnick: “The president was talking about this all day on Saturday....He was talking about ‘we got to drive*

these prices down.”).³ Notwithstanding the President’s emphatic declarations, Lilly continues to charge Americans higher prices than patients in foreign countries, as explained in Petitioner’s briefing. DDO, 52-54; EX1078; EX1084. By granting Lilly’s discretionary denial request, the Administration risks leaving itself toothless to correct Lilly’s prosecution error. There is no reason for the Executive branch to divest itself of its Constitutional and statutory error-correction power against Lilly now, especially while Lilly’s commitments to fair drug pricing and production onshoring remain inchoate and incomplete. *See* R. Robbins et al., *Obesity Drugs May Drop to as Little as \$149 a Month*, N.Y. Times (Nov. 8, 2025) (“The prices Britain pays are still lower than the new direct-buy prices Trump officials negotiated in the United States.”).⁴ It is inconceivable that this Administration would capitulate to Lilly while the President’s goals remain anything less than completely fulfilled.

Indeed, the very pendency of Petitioner’s Director Review request returns the balance of power back to the Executive, retaining to him the discretion to correct Lilly’s erroneous patent grant in the future should sufficient Office resources

³ Available at <https://www.axios.com/2025/09/12/trump-drug-prices-howard-lutnick>.

⁴ Available at <https://www.nytimes.com/2025/11/06/health/obesity-drug-prices-trump.html>.

become available. As there is no statutory deadline for deciding Director Review requests, and knowing the Director's watchful eye is examining the important issues raised in Petitioner's briefing can only incentivize Lilly to avoid further misconduct, prudence dictates that the Director should reserve for himself ample time to fully consider Petitioner's meritorious arguments. The Director thus should reject Lilly's attempts to summarily displace the Executive from his Constitutional and statutorily-mandated power to revisit Lilly's patent grant.

V. CONCLUSION

Despite clear and correctable Patent Office error that Lilly invited, Lilly overcharges the very American taxpayers this Administration champions. Empower respectfully asks the Director to prevent an outcome so clearly contrary to both Office and Administration policy.

Respectfully submitted,

Dated: November 10, 2025

/ Jad A. Mills /

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Counsel, Empower Clinic Services, L.L.C.

VI. CERTIFICATE OF SERVICE

I certify that today this paper was served electronically on Eli Lilly & Co.'s counsel at michael.morin@lw.com; david.frazier@lw.com; michelle.ernst@lw.com; inge.osman@lw.com; raghav.bajaj@lw.com; ashley.fry@lw.com; hostettler_danica@lilly.com; barkoff_aaron@lilly.com. See Paper 8 (PO Updated Mand. Not.).

All statements in this certificate of service made of my own knowledge are true and all statements made on information and belief are believed to be true. I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of this proceeding.

Dated: November 10, 2025

/ Christopher Kielman /
Christopher Kielman