

Filed on behalf of: Eli Lilly & Co.

Entered: October 2, 2025

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 9,474,780

**PATENT OWNER'S REPLY IN SUPPORT OF ITS REQUEST FOR
DISCRETIONARY DENIAL**

Petitioner's Opposition rests on baseless allegations (that Lilly intentionally hid references it called out repeatedly in the specification), speculation (that the Examiner was unaware of art cited in both the specification and the Examiner-requested Search Results, which Petitioner omitted from its file history "Excerpts"), and cropped quotes (*e.g.*, from the Reasons for Allowance). When rhetoric is sieved from substance, it is readily apparent that the Director should deny institution.

I. The Examiner Considered the Same or Cumulative Art and Arguments

Petitioner, for the first time in this proceeding, accuses Lilly of deliberately concealing prior art, baselessly arguing that Lilly "invited" examiner error and that Lilly's tirzepatide patent is "unenforceable." Opp. 2, 4-5, 6, 15, 51-52, 56-57, 63. That is demonstrably false. Lilly cited Alsina-Fernandez twice in the '780 patent specification, including in the very first column, and identified Lau's core subject matter (semaglutide) 28 times throughout the specification. '780 patent, 1:55-57, 20:63-64, 8:23-26, 22:18-28:16; Tables 7-9, 11-12, 14-15. Further, Lilly explained that Alsina-Fernandez disclosed "[c]ertain GIP analogs" with "both GIP and GLP-1 activity," *id.*, 1:55-57, and directed the Examiner to semaglutide's structure, *id.* 8:23-26 ("semaglutide'... has the peptide backbone and overall compound structure of that found in CAS Registry Number 910463-68-2").

Petitioner nevertheless asserts there "is no indication" that Alsina-Fernandez was before the Examiner and "no evidence" the Examiner considered it or Lau. Opp.

19-20, 26, 34, 56. That too is false. Petitioner's excerpted '780 patent file history, Ex. 1004, conspicuously omits the Examiner's Search Results, which further establish that she considered the relevant disclosures of both references. Ex. 2088 (Search Results dated July 14, 2016, <https://data.uspto.gov/patent-file-wrapper/search/details/14987791/documents>). The Examiner's Search Results identify Alsina-Fernandez and its SEQ ID NOs:1-5 (all of which are within the scope of Petitioner's "lead compound") *in its first four pages*. *Id.* 3-4. It also includes Lau's relevant disclosure, referring to semaglutide twelve times and disclosing structures with the claimed albumin binding moieties more than two dozen times. *Id.* 10, 17, 54, 74-80, 82, 85-92, 95, 99-104, 108-20, 124, 156, 162. 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.¹

II. Petitioner Failed to Identify Any Material Error By The Examiner

Petitioner's primary allegation of material error is that the Examiner believed

¹ In *Siemens Mobility, Inc. v. MetroM Rail, LLC*, IPR2024-00947, Paper 16 (P.T.A.B. Apr. 4, 2025), merely including a patent number in a search query did not make the patent of record where that use did not establish that the Examiner was presented with the patent's disclosures. *Id.* at 11-12. But here, the Examiner *was* presented with the relevant disclosures, in both the specification and Search Results.

a single amino acid, glutamine at position 24 (“Gln24”), and an albumin binding moiety were absent from the prior art. Opp. 1-3, 7-8. Petitioner mischaracterizes the Examiner’s findings, cropping a key quote to support its false narrative. Opp. 8. Specifically, in the portion of the Reasons for Allowance omitted by Petitioner, the Examiner expressly stated that “[e]ven if” Gln24 were disclosed, the claims would still be nonobvious, because “hindsight reasoning” would be required to arrive at the claimed compounds. Ex. 1004, 27-28. Tellingly, Petitioner’s cropped quote ends immediately before the words “hindsight reasoning.” Opp. 8.

The Reasons for Allowance also dispose of Petitioner’s argument that Alsina-Fernandez “closed the gap” between the claims and the prior art. Opp. 24. The “gap” remains, as the Examiner’s comments about the need to “choose options” and use “hindsight reasoning” to reach the claimed compounds apply equally to Alsina-Fernandez as they do to Just. *See* POPR 13-15, 22-54.

Petitioner further misrepresents the Reasons for Allowance, asserting that the Examiner limited her analysis to “preferred” disclosures in Just and failed to account for allegedly-predictable SAR relationships. Opp. 10-11. Not so. She specifically looked beyond the preferred and reduced-to-practice embodiments, relying on, e.g., sub-genera II(b), II(c), and II(d), and explaining that “most of the species disclose[d] in [Just] lack the GPSSGAPPPS sequence” and that the species “that are conjugated to a lipophilic substituent[] are conjugated to hexedecanoyla-isoGlu at lysine 17, not

at lysine 20.” Ex. 1004, 28. She correctly understood the field was highly unpredictable and hindsight would be required to make the many changes from the prior art to the claimed compounds. Ex. 1004, 27-28; POPR 13-15, 22-54.

III. Petitioner's Shifting Arguments Highlight Their Weakness

Petitioner uses its Opposition to try to cure deficiencies in its Petition, eschewing its original arguments in favor of new ones. For example, when faced with extensive evidence that Petitioner's lead compound analysis is legally deficient, DD 38-49; POPR 16-22, Petitioner does an about-face, arguing that no lead compound analysis is necessary. Opp. 5, 41.

In addition to being procedurally improper, Petitioner's arguments are legally wrong. Petitioner relies on *Cytiva BioProcess R&D AB v. JSR Corp.*, 122 F.4th 876 (Fed. Cir. 2024), to argue the lead compound test is unnecessary. But there, the Federal Circuit found the test unnecessary because the prior art “expressly disclose[d]” the proposed modification. *Id.* at 884-85. While Petitioner asserts that the prior art “expressly identi[fied] a compound” and “expressly proposed its further modification,” (Opp. 2, 45), there is no express teaching *anywhere* to modify Alsina-Fernandez with the numerous, specific, changes necessary to arrive at the claims, as would be required to sidestep the lead compound requirement. And Petitioner's characterization of Alsina-Fernandez as “most promising” is wishful thinking: those words appear only in the Petition, not in the prior art. Opp. 45; see Pet. 25.

IV. Lilly's Strong Settled Expectations Warrant Denial

Petitioner does not dispute that it has known of the '780 patent for years and could have challenged it far earlier. Yet Petitioner blames Lilly for its own decision not to seek review of the patent when it first started selling its knockoff version of tirzepatide, and asks the Director to ignore Lilly's strong settled expectations.

Petitioner goes so far as to argue that Lilly does not have settled expectations because Lilly has not asserted the '780 patent against it. Opp. 58. That is nonsense. Not asserting a patent does not preclude strong settled expectations. *See, e.g., Sig Sauer Inc. v. Lone Star Future Weapons, Inc.*, IPR2025-00410, Paper 13 at 2 (P.T.A.B. June 26, 2025). Instead, settled expectations also considers whether the patent has been commercialized and applied, not merely whether it has been asserted. *Intel Corp. v. Proxsense LLC*, IPR2025-00327, -00328, 00329, Paper 12 (P.T.A.B. June 26, 2025). Here, it is undisputed that the '780 patent has been commercialized and applied widely in the pharmaceutical space. DD 13-20.

And while Petitioner tries to tell a public interest story, it is Lilly that has relied on the '780 patent and its protection of Lilly's blockbuster products in committing \$50 billion to U.S. infrastructure and creating thousands of U.S. jobs. Far from undermining the Executive, Lilly's positions recognize that this Executive was the first, despite a decade of PTAB practice, to address the importance of settled expectations for patents, like this one, underlying hallmark American innovations.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 2nd day of October, 2025, a true and correct copy of the foregoing **Patent Owner's Reply In Support Of Its Request For Discretionary Denial** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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