

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 SURREPLY OPPOSING
LILLY'S DISCRETIONARY-DENIAL REQUEST

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Repetition Just Compounds The Material Error.....	1
III.	Consistent, Alternate Cases Remain Unrebutted.....	4
IV.	Lilly’s Silence Shows Unsettled Expectations	5
V.	Conclusion	5
VI.	Certificate of Service	7

TABLE OF AUTHORITIES

Cases

<i>KSR Int’l v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	4
<i>Samsung Electronics v. Wilus Institute of Standards and Technology</i> , IPR2025-00935, Paper 12 (USPTO Dir. 2025)	3
<i>Siemens Mobility v. Metrom Rail</i> , IPR2024-00947, Paper 16 (USPTO Dir. 2025)	3

Statutes

35 U.S.C. 316(b)	5
------------------------	---

Other Authorities

J.C. Squires, <i>Questions from Senator Grassley</i>	5
--	---

I. INTRODUCTION

Despite yet another opportunity to brief discretionary denial, Patent Owner (Lilly) itself demonstrates that discretionary denial would be inappropriate here. Remarkably, Lilly's new exhibit (EX2088) confirms material error and demonstrates the examiner never considered the teachings of EX1007—Lilly's new exhibit even shows why. The remainder of Lilly's reply (DDRep.) simply rehashes previous, failed arguments. This case should be referred to a merits panel.

II. REPETITION JUST COMPOUNDS THE MATERIAL ERROR

Lilly now produces EX2088, which simply confirms material error. Not only did the examiner not cite the portions of the search report Lilly now cites, but the 220-page report itself is one of 105 search results under Supplemental Content in the electronic filewrapper. Supplemental Content, Search Results (105), <https://patentcenter.uspto.gov/applications/14987791>. Though Lilly never discusses it, at best, the examiner merely notes a “Commercial database structure and text search – see SCORE | 7/14/2016 | STIC”.¹ EX1004, 47 (Search Notes).

Worse yet (for Lilly), EX2088 indicates *why* the examiner materially erred. The examiner made a reasonable search request for the sequence in Lilly's claim 1,

¹ Presumably, “STIC” refers to USPTO's Scientific and Technical Information Center because the examiner's initials are “CMB”.

emphasizing “the fragment KIAQKAXVQ at positions 16-24” and discounting the importance of “the lysine at position 20.” EX2088-001. The search purportedly returned EX2088, which lists as the best match “PN: WO2013164483 SEQID: 5 unclaimed sequence”. EX2088-002. Hence, the examiner instead considered WO’483 (Just) but found it distinguishable. EX1004, 27 (Reasons for Allowance). The examiner never cited “PN: WO2011119657 SEQID:1 claimed protein”, which appears later in the search report, probably because STIC provided a defective result. Hence, the examiner mistakenly considered WO’483 (Just) the closest prior art.

As the petition explains, EX1007’s claimed SEQ ID NO:1 (which is not in WO’483) aligns with Lilly’s claimed sequences as shown (right). But EX2088-004 provides a

Tyr-Aib-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-Aib-Leu-										
5					10					
Asp-Lys-Ile-Ala-Gln-Arg-Ala-Xaa ¹ -Val-Gln-Trp-Leu-Ile-Ala-										
15	20					25				
Aib-Lys-Gly-Lys-Lys-Gln-Glu-Trp-Lys-His-Gln-Ile-Thr-Gln-										
30			35			40				
Xaa ² -Xaa ³ (SEQ ID NO:1)										

much less promising hit map, which missed all the hits marked in green (below).

STIC failed the examiner by ignoring her targeted

CN	1:	PN:	WO2011119657	SEQID:	1	claimed	protein
CI	MAN						
SQL	44						
SEQ	1	YXE	GTFTSDY	SIX	LDKIAQR	AXVQWLIA	XX GKKQEWKHQI TQXX
		=====		=====			
HITS AT:	4-11, 14-19						

“KIAQKAXVQ” sequence (discounting the K at position 20), thus missing half of critical peptide hits the examiner sought. This is **Office** error, whether one attributes it to STIC’s faulty results or the examiner’s failure to check the accuracy of STIC’s

results. Instead, the examiner went with the first hit (Just, in which the examiner evaluated a very broad genus). No wonder the examiner materially erred. To err is human, to fix a known, material err is the responsible thing to do.

Lilly continues to assert the examiner “considered” EX1007 and references cumulative to EX1009—without identifying any actual examiner consideration—now based on a document buried in the Supplemental Content that the examiner never initialed. DDRep. 1-2. In *Samsung Electronics v. Wilus Institute of Standards and Technology*, the Director explained that despite a collateral trial likely to end sooner, examiner error warranted a referral. IPR2025-00935, Paper 12, 2 (USPTO Dir. 2025) (“Petitioner provides persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims by overlooking the [ground reference’s] teachings.”). Samsung had noted that “[t]he Examiner’s search ... failed to adequately investigate prior art from the top assignee ... identified to the Examiner multiple times during examination.” IPR’935-DDOpp. 3. *See also Siemens Mobility v. Metrom Rail*, IPR2024-00947, Paper 16, 11-12 (USPTO Dir. 2025) (which Lilly fails to distinguish, DDRep. 2 n.1, because Lilly asserts—but cannot even show a similar level of—examiner consideration). Thus, contrary to Lilly’s implicit assumption, the presence—indeed, the pervasive presence—of prior art from the same applicant does not rebut error by proving consideration; instead, it eloquently highlights how badly the materiality of the reference was overlooked.

Lilly's conclusory citation to even later pages in EX2088 to allegedly render EX1009 cumulative fails for the same reason: Lilly does not show the examiner considered EX1009 or EX1010 in any form, much less rendered them cumulative. See Paper 11 (DDOpp.), *e.g.*, 3-4, 7, 9-10, 13-14, 16, 24-25, 27, 29-30, 32, 34-36 (unrebutted discussion of how EX1010 shows EX1009 provides key, unconsidered motivation).

III. CONSISTENT, ALTERNATE CASES REMAIN UNREBUTTED

Lilly asserts Empower “shift[s] arguments,” DDRep. 4, but Empower's petition and DDOpp. are consistent: Empower wins under **both** a lead-compound **and** a standard *KSR* analysis. Empower's DDOpp. necessarily and properly focused on Lilly's DDReq. arguments, which distorted lead-compound law, rather than rehashing the petition. Now, Lilly mischaracterizes Empower's obviousness argument to battle a strawman. The petition explained how EX1007 expressly provided a promising starting point **and** suggested evaluating structurally-similar peptides. Pet. 24-25. Lilly's argument now is essentially that the petition's showing was not enough because EX1007 did not anticipate **all** modifications, DDRep. 4 (“there is no express teaching **anywhere** to modify [EX1007] with the numerous, specific, changes necessary to arrive at the claims” (original emphasis)), which is not even remotely a requirement for chemical obviousness under any test.

IV. LILLY’S SILENCE SHOWS UNSETTLED EXPECTATIONS

At DDRep. 5, Lilly again tries to change the subject: Lilly lauds commercial success that it attributes to its ’780 patent but cannot explain why it does not enforce this supposedly valuable patent. Instead, Lilly asserts the red herring that it need not sue, DDRep. 5, which is true but irrelevant. Significantly, Lilly does not rebut the inference that an objective, reasonable patentee would enforce such a “valuable” patent unless it is a really a lemon. Lilly’s silence is deafening.

Lilly appeals to this Administration’s commitment to patentee expectations, while ignoring the Administration’s even greater commitment to patent quality. Lilly did not, and cannot, show that its continued profiteering against American patients on a mis-examined patent is somehow consonant with Administration policy. 35 U.S.C. 316(b); *see also* J.C. Squires, *Questions from Senator Grassley*, Response 1 (emphasizing patent quality), at https://www.judiciary.senate.gov/imo/media/doc/2025-05-21_qfrresponses_squires.pdf.

V. CONCLUSION

Despite multiple, generous chances, Lilly fails yet again to show discretionary denial is warranted. Lilly’s reply is self-defeating. Its new exhibit confirms the examiner never considered EX1007 and also shows why. Lilly’s other arguments also fail. The petition should be referred to a panel for institution.

Respectfully submitted,

Dated: October 6, 2025

/ *Jad A. Mills* /

Jad A. Mills, Reg. No. 63,344
Counsel, Empower Pharmaceuticals, Inc.

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: October 6, 2025

/ Yawen Wang /
Yawen Wang