

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 UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner respectfully submits the following updated Exhibit List:

Exhibit	Description
2001	International Patent Publication No. WO 2014/192284 A1 (“Asami”)
2002	Press Release, Eli Lilly & Co., FDA Approves Lilly’s Mounjaro™ (Tirzepatide) Injection, the First and Only GIP and GLP-1 Receptor Agonist for the Treatment of Adults With Type 2 Diabetes (May 13, 2022), https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-mounjaro-tm-tirzepatide-injection-first-and
2003	PhRMA, <i>Research and Development Policy Framework</i> (updated Sept. 2024), https://www.phrma.org/policy-issues/research-development (last visited Aug. 18, 2025)
2004	Max Beuroyre, <i>Clinical-Trial Costing 101: Building a Phase-By-Phase Budget Your Board Will Trust</i> , Abacum (June 25, 2025), https://www.abacum.ai/blog/clinical-trial-costing (last visited Aug. 14, 2025)
2005	Certified Clinical Rsch. Pros. Soc’y (CCRPS), <i>Phase III Clinical Trials: Definitive Guide & Case Studies</i> (June 8, 2025), https://ccrps.org/clinical-research-blog/phase-iii-clinical-trials-definitive-guide-amp-case-studies#:~:text=Why%20are%20Phase%20III%20trials,costly%20phase%20in%20drug%20development (last visited Aug. 14, 2025)
2006	Fierce Healthcare, <i>U.S. Phase IV Budgets Top \$12,000 Per Patient</i> (Sept. 23, 2011, 12:21 P.M.), https://www.fiercehealthcare.com/healthcare/u-s-phase-iv-budgets-top-12-000-per-patient (last visited Aug. 19, 2025)

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2007	Johns Hopkins Univ., Bloomberg Sch. of Pub. Health, <i>Cost of Clinical Trials For New Drug FDA Approval Are Fraction of Total Tab</i> (Sept. 24, 2018), https://publichealth.jhu.edu/2018/cost-of-clinical-trials-for-new-drug-FDA-approval-are-fraction-of-total-tab (last visited Aug. 8, 2025)
2008	RESERVED
2009	Eli Lilly & Co., <i>A Study of Tirzepatide (LY3298176) in Healthy Participants and Participants With Type 2 Diabetes (T2DM)</i> , Nat'l Inst. of Health (NIH), Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., ClinicalTrials.gov ID No. NCT02759107 (June 26, 2017), https://clinicaltrials.gov/study/NCT02759107 (last visited Aug. 8, 2025)
2010	Tamer Coskun et al., <i>LY3298176, a Novel Dual GIP and GLP-1 Receptor Agonist for the Treatment of Type 2 Diabetes Mellitus: From Discovery to Clinical Proof of Concept</i> , 18 Molecular Metabolism 3 (2018), https://www.sciencedirect.com/science/article/pii/S2212877818309001?via%3Dihub
2011	Eli Lilly & Co., Earnings Presentation: Q2 2016 Financial Review (July 26, 2016), https://investor.lilly.com/static-files/1d298757-bf8e-4c89-932a-77b25d79289e
2012	S&P Glob. Mkt. Intel., Eli Lilly & Co. NYSE:LLY FQ3 2017 Earnings Call Transcripts (Oct. 24, 2017, 1:00 P.M. GMT)
2013	Press Release, Eli Lilly & Co., Lilly's Investigational Dual GIP and GLP-1 Receptor Agonist Shows Significant Reduction in HbA1c and Body Weight in People With Type 2 Diabetes (Oct. 4, 2018), https://investor.lilly.com/news-releases/news-release-details/lilys-investigational-dual-gip-and-glp-1-receptor-agonist-shows#:~:text=INDIANAPOLIS%20%2C%20Oct.,people%20with%20type%20%20diabetes .

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2014	Juan Pablo Frias et al., <i>Efficacy and Safety of LY3298176, a Novel Dual GIP and GLP-1 Receptor Agonist, in Patients With Type 2 Diabetes: A Randomised, Placebo-Controlled and Active Comparator-Controlled Phase 2 Trial</i> , 392 Lancet 2180 (2018), http://dx.doi.org/10.1016/S0140-6736(18)32260-8
2015	Pharm. Tech., <i>Lilly Reports Positive Results for GIP/GLP-1 RA Type 2 Diabetes Trial</i> (Oct. 5, 2018), https://www.pharmaceutical-technology.com/news/lilly-type-2-diabetes-trial/?cf-view&cf-closed (last visited Aug. 19, 2025)
2016	Carly Helfand, <i>Lilly Makes Waves With Next-Generation Diabetes Drug, But GLP-1 Rivals Needn't Panic: Analysts</i> , Fierce Pharma (Oct. 8, 2018, 10:40 A.M.), https://www.fiercepharma.com/marketing/lilly-makes-waves-positive-data-next-gen-diabetes-prospect (last visited Aug. 20, 2025)
2017	Press Release, Eli Lilly & Co., <i>Lilly's Tirzepatide Significantly Reduced A1C and Body Weight in People With Type 2 Diabetes</i> (Dec. 9, 2020), https://investor.lilly.com/news-releases/news-release-details/lillys-tirzepatide-significantly-reduced-a1c-and-body-weight
2018	Press Release, Eli Lilly & Co., <i>Tirzepatide Significantly Reduced A1C and Body Weight in People With Type 2 Diabetes in Two Phase 3 Trials from Lilly's SURPASS Program</i> (Feb. 17, 2021), https://investor.lilly.com/news-releases/news-release-details/tirzepatide-significantly-reduced-a1c-and-body-weight-people
2019	Press Release, Eli Lilly & Co., <i>Lilly's SURPASS-2 Results Published in The New England Journal of Medicine Show Tirzepatide Achieved Superior A1C and Body Weight Reductions Compared to Injectable Semaglutide in Adults With Type 2 Diabetes</i> (June 25, 2021), https://investor.lilly.com/news-releases/news-release-details/lillys-surpass-2-results-published-new-england-journal-medicine

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2020	Press Release, Eli Lilly & Co., Lilly's Tirzepatide Reduced Obstructive Sleep Apnea (OSA) Severity, With Up to 51.5% of Participants Meeting the Criteria for Disease Resolution (June 21, 2024), https://investor.lilly.com/news-releases/news-release-details/lillys-tirzepatide-reduced-obstructive-sleep-apnea-osa-severity
2021	Juan P. Frias et al., <i>Tirzepatide Versus Semaglutide Once Weekly in Patients With Type 2 Diabetes</i> , 385 NEJM 503 (2021), https://www.nejm.org/doi/pdf/10.1056/NEJMoa2107519
2022	Bernhard Ludvik et al., <i>Once-Weekly Tirzepatide Versus Once-Daily Insulin Degludec as Add-on to Metformin With or Without SGLT2 Inhibitors in Patients With Type 2 Diabetes (SURPASS-3): A Randomised, Open-Label, Parallel-Group, Phase 3 Trial</i> , 398 Lancet 583 (2021), https://doi.org/10.1016/S0140-6736(21)01443-4
2023	Ania M. Jastreboff et al., <i>Tirzepatide Once Weekly for the Treatment of Obesity</i> , 387 NEJM 205 (2022), https://www.nejm.org/doi/pdf/10.1056/NEJMoa2206038
2024	Thomas A. Wadden et al., <i>Tirzepatide After Intensive Lifestyle Intervention in Adults With Overweight or Obesity: The SURMOUNT-3 Phase 3 Trial</i> , 29 Nature Med. 2909 (2023), https://www.nature.com/articles/s41591-023-02597-w
2025	Gina Kolata, <i>Patients Taking Experimental Obesity Drug Lost More Than 50 Pounds, Maker Claims</i> , N.Y. Times (Apr. 28, 2022; updated May 1, 2022), https://www.nytimes.com/2022/04/28/health/obesity-drug-eli-lilly-tirzepatide-wegovy.html (last visited Aug. 5, 2025)
2026	Mitchel L. Zoler, <i>Tirzepatide Powers 'Unprecedented' Weight Loss in Obesity Trial</i> , Medscape (June 4, 2022), https://www.medscape.com/viewarticle/975061?form=fpf-loss-drugs-asparadigm-shifting-while-cautioning-on-safety-and-cost (last visited Aug. 20, 2025)

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2027	Julio Rosenstock et al., <i>Achieving Normoglycemia With Tirzepatide: Analysis of SURPASS 1–4 Trials</i> , 46 Diabetes Care 1986 (2023), https://diabetesjournals.org/care/article/46/11/1986/153571/Achieving-Normoglycemia-With-Tirzepatide-Analysis
2028	Rachel Hosie, <i>A Highly Anticipated Weight-Loss Drug Helped People Lose Over 20% of Their Weight in a Late-Stage Clinical Trial, Study Finds</i> , Bus. Insider (June 6, 2022, 10:03 A.M. UTC), https://www.businessinsider.com/weight-loss-drug-helped-people-lose-20-bodyweight-study-tirzepatide-2022-4 (last visited Aug. 15, 2025)
2029	[Corrected] Vivek P. Chavda et al., <i>Tirzepatide, A New Era of Dual-Targeted Treatment for Diabetes and Obesity: A Mini-Review</i> , 27 Molecules 4315 (2022), https://www.mdpi.com/1420-3049/27/13/4315
2030	Peter Loftus, <i>The ‘King Kong’ of Weight-Loss Drugs Is Coming</i> , Wall St. J. (Apr. 3, 2023, 10:31 A.M. ET), https://www.wsj.com/health/pharma/ozempic-mounjaro-weight-loss-drug-wegovy-eli-lilly-66f2906?gaa_at=eafs&gaa_n=ASWzDAiR9Pc6-Ryib2hY53uy1DuXiuWbjaLU2gLy9R26e89ceFbFONZqZ3BZ&gaa_ts=68a5d86a&gaa_sig=ypayOSSwVtXED8GLKuCY9Et7WcrX0ColSaeEazh0zo_jG5e4_fiEXrFyUjHNo23X7kbw7LsLgcXGO8rXybAgfg%3D%3D (last visited Aug. 20, 2025)
2031	Brian Buntz, <i>Why Lilly’s Tirzepatide Has Blockbuster Potential</i> , Drug Discovery Dev. (June 3, 2021), https://www.drugdiscoverytrends.com/why-lillys-tirzepatide-has-blockbuster-potential/ (last visited Aug. 19, 2025)

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2032	Brian Buntz, <i>Lilly's Tirzepatide Gives Novo Nordisk's Semaglutide a Run for the Money in Phase 3 Trial</i> , Drug Discovery Dev. (Apr. 28, 2022), https://www.drugdiscoverytrends.com/lillys-tirzepatide-gives-novo-nordisks-semaglutide-a-run-for-the-money-in-phase-3-trial/ (last visited Aug. 5, 2025)
2033	Asher Mullard, <i>Lilly's Tirzepatide Secures First Approval in Diabetes, Paving Path for Dual-Acting Hormone Mimetics</i> , Nature Revs. Drug Discovery (May 20, 2022), https://www.nature.com/articles/d41573-022-00094-2 (last visited Aug. 15, 2025)
2034	Biopharma PEG, <i>FDA Approves Tirzepatide, A Potential Blockbuster Drug for Type 2 Diabetes</i> (May 20, 2022, 14:32:06), https://www.biochempeg.com/article/268.html (last visited Aug. 5, 2025)
2035	Lijing Wang, <i>Designing a Dual GLP-1R/GIPR Agonist from Tirzepatide: Comparing Residues Between Tirzepatide, GLP-1, and GIP</i> , 16 Drug Design Dev. Therapy 1547 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9149770/pdf/dddt-16-1547.pdf
2036	Natalie Sainz, <i>Overcoming Challenges in Obesity Medicine: The SURMOUNT Clinical Development Program</i> , diaTribe Learn (Sept. 21, 2022), https://diatribe.org/diabetes-research/overcoming-challenges-obesity-medicine-surmount-clinical-development-program (last visited Aug. 5, 2025)
2037	Drs. Bus. Network, <i>Unlocking the Potential of Tirzepatide: A New Era in Treatment</i> (Apr. 28, 2025), https://blog.doctorsbusinessnetwork.com/tirzepatide-unlocking-the-p/ (last visited Aug. 5, 2025)
2038	Brian Buntz, <i>GLP-1 Drug Tirzepatide Shines in SURMOUNT-3 Trial With Weight Loss of 26.6%</i> , Drug Discovery Dev. (Oct. 16, 2023), https://www.drugdiscoverytrends.com/tirzepatide-surmount-3-trial-results/ (last visited Aug. 20, 2025)

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2039–2040	RESERVED
2041	Zacks Equity Rsch. for Zacks, <i>Lilly's (LLY) Tirzepatide Meets Endpoints in Late-Stage Study</i> , Nasdaq (Dec. 10, 2020, 10:56 A.M. EST), https://www.nasdaq.com/articles/lillys-lly-tirzepatide-meets-endpoints-in-late-stage-study-2020-12-10 (last visited Aug. 8, 2025)
2042	Press Release, Eli Lilly & Co., FDA Approves Lilly's Zepbound™ (tirzepatide) for Chronic Weight Management, A Powerful New Option for the Treatment of Obesity or Overweight With Weight-Related Medical Problems (Nov. 8, 2023), https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-zepboundtm-tirzepatide-chronic-weight
2043	Press Release, Eli Lilly & Co., FDA Approves Zepbound® (tirzepatide) as the First and Only Prescription Medicine for Moderate-to-Severe Obstructive Sleep Apnea in Adults With Obesity (Dec. 20, 2024), https://investor.lilly.com/news-releases/news-release-details/fda-approves-zepboundr-tirzepatide-first-and-only-prescription
2044	<i>Tirzepatide (Mounjaro (Autoinjector)) Solution 5mg/0.5ml (5mg/0.5ml)</i> , Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations, U.S. Food & Drug Admin. (FDA), https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=215866&Appl_type=N (last visited Aug. 8, 2025)
2045	PubChem, Substance Rec. 910463-68-2, Nat'l Lib. of Med., Nat'l Ctr. for Biotechnology Info., https://pubchem.ncbi.nlm.nih.gov/substance/135267256/version/1 (last visited Aug. 8, 2025)
2046	Duxin Sun et al., <i>Why 90% of Clinical Drug Development Fails and How to Improve It?</i> , 12 Acta Pharmaceutica Sinica B 3049 (2022), https://www.sciencedirect.com/science/article/pii/S2211383522000521?via%3Dihub

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2047	Biotechnology Innovation Org. (BIO) et al., <i>Clinical Development Success Rates and Contributing Factors 2011–2020</i> (Feb. 2021), https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf
2048	Helen Dowden & Jamie Munro, <i>Trends in Clinical Success Rates and Therapeutic Focus</i> , 18 <i>Nature Revs. Drug Discovery</i> 495 (2019), https://media.nature.com/original/magazine-assets/d41573-019-00074-z/d41573-019-00074-z.pdf
2049	Eli Lilly & Co., Tirzepatide Clinical Studies Listing, Clinicaltrials.gov (last visited Aug. 19, 2025), https://clinicaltrials.gov/search?intr=Tirzepatide&spons=Eli%20Lilly%20and%20Company
2050	Eli Lilly & Co., Tirzepatide Non-NCT Clinical Trials (compilation) (https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12623001236684 (last visited Aug. 14, 2025); https://jrct.mhlw.go.jp/en-latest-detail/jRCT1051240017 (last visited Aug. 14, 2025); https://catalogues.ema.europa.eu/node/3777/administrative-details (last visited Aug. 14, 2025))
2051-2052	RESERVED
2053	Timo D. Müller et al., <i>Anti-Obesity Drug Discovery: Advances and Challenges</i> , 21 <i>Nature Revs. Drug Discovery</i> 201 (2022), https://www.nature.com/articles/s41573-021-00337-8
2054	U.S. Patent No. 11,357,820 (B2)
2055-2056	RESERVED
2057	Lotte B. Knudsen, <i>GLP-1 Derivatives as Novel Compounds for the Treatment of Type 2 Diabetes: Selection of NN2211 for Clinical Development</i> , 26 <i>Drugs Future</i> 677 (2001), https://doi.org/10.1358/dof.2001.026.07.628723
2058	RESERVED

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2059	W. Gattrell et al., <i>Designed Multiple Ligands in Metabolic Disease Research: From Concept to Platform</i> , 18 Drug Discovery Today 692 (2013), https://www.sciencedirect.com/science/article/abs/pii/S135964461300041X
2060	RESERVED
2061	Luminita Timofte et al., <i>Exenatide and Liraglutide – Side Effects. Comparative Clinical Study</i> , 61 Farmacia 837 (2013), https://farmaciajournal.com/issue-articles/exenatide-and-liraglutide-side-effects-comparative-clinical-study/
2062	Christopher JL Kueh & Miles Fisher, <i>Taspoglutide</i> , 31 Prac. Diabetes 393 (2014), https://wchh.onlinelibrary.wiley.com/doi/epdf/10.1002/pdi.1911
2063	Lotte B. Knudsen et al., <i>Potent Derivatives of Glucagon-Like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration</i> , 43 J. Med. Chemistry 1664 (2000), https://pubs.acs.org/doi/10.1021/jm9909645
2064	U.S. Patent Application Publication No. 2016/0015788 A1 (“Holscher”)
2065	Yongsheng Gao et al., <i>PEGylated Therapeutics in the Clinic</i> , 9 Bioengineering Translational Med. 1–28 (2023), https://aiche.onlinelibrary.wiley.com/doi/epdf/10.1002/btm2.10600
2066	Martin Lorenz et al., <i>Recent Progress and Future Options in the Development of GLP-1 Receptor Agonists for the Treatment of Diabetes</i> , 23 Bioorganic Med. Chemistry Letters 4011 (2013), https://www.sciencedirect.com/science/article/pii/S0960894X13006082?via%3Dihub
2067	Shaolei Teng et al., <i>Structural Assessment of the Effects of Amino Acid Substitutions on Protein Stability and Protein–Protein Interaction</i> , 3 Int’l J. Computational Biology Drug Design 334 (2010), https://www.inderscienceonline.com/doi/abs/10.1504/IJCBDD.2010.038396

Exhibit	Description
2068–2072	RESERVED
2073	Mounjaro [®] Prescribing Information (revised May 2025)
2074	Zepbound [®] Prescribing Information (revised Feb. 2025)
2075	Empower Pharmacy, <i>Understanding GLP-1s</i> , https://www.empowerpharmacy.com/compound-medication/weight-management/understanding-glp-1-receptor-agonists/ (last visited Sept. 8, 2025)
2076	Francis S. Willard et al., <i>Tirzepatide Is An Imbalanced and Biased Dual GIP and GLP-1 Receptor Agonist</i> , 5 JCI Insight 1–16 (2020), https://insight.jci.org/articles/view/140532
2077	Press Release, FDA, FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes (May 13, 2022), https://web.archive.org/web/20220522112919/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes
2078	Press Release, FDA, FDA Approves New Medication for Chronic Weight Management (Nov. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management
2079	The Galien Foundation, <i>The Galien Foundation Honors 2023 Prix Galien Award Recipients</i> , PR Newswire (Oct. 27, 2023, 9:00 ET), https://www.prnewswire.com/news-releases/the-galien-foundation-honors-2023-prix-galien-award-recipients-301969840.html
2080	The Galien Foundation, <i>The Prix Galien USA Is America's Preeminent Prize Acknowledging the Leading-Edge of Scientific Advances in Life Sciences Since 2007</i> , https://www.galienfoundation.org/prix-galien-usa (last visited Sept. 8, 2025)
2081	Eli Lilly & Co., Annual Report (Form 10-K) (Feb. 19, 2025)

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2082	Statista, Chart: Leading Drugs Worldwide Based on Projected 2025 Sales (in Billion U.S. Dollars) (Dec. 2024) (obtained from Evaluate (EvaluatePharma) and Nature Reviews Drug Discovery)
2083	RESERVED
2084	Rachel Sinha et al., <i>Efficacy and Safety of Tirzepatide in Type 2 Diabetes and Obesity Management</i> , 32 J. Obesity Metabolic Syndrome 25 (2023), https://www.jomes.org/journal/view.html?doi=10.7570/jomes22067
2085	Empower Pharmacy, <i>About Us: We're Making Healthcare Personal</i> , https://www.empowerpharmacy.com/about/ (last visited Sept. 16, 2025)
2086	Press Release, Eli Lilly & Co., Lilly Reports Second-Quarter 2025 Financial Results and Raises Guidance (Aug. 7, 2025), https://investor.lilly.com/static-files/afdc26aa-05ac-477a-ac41-9c414da09e2f
2087	Eli Lilly & Co., Presentation: Q2 2025 Earnings Call (Aug. 7, 2025), https://investor.lilly.com/static-files/b7c7e82b-e667-42ba-827c-1faecba3e4c8
2088	Search Results in file history for U.S. Patent No. 9,474,780 (July 14, 2016), https://data.uspto.gov/patent-file-wrapper/search/details/14987791/documents

Respectfully submitted,

Dated: October 2, 2025

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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 Updated Exhibit List and Exhibit 2088** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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