UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICAL INDUSTRIES LTD., AND SUN PHARMACEUTICAL INDUSTRIES, INC.

Petitioner,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2023-00724[1]

Patent No. 10,335,462

UPDATED LIST OF PETITIONER'S EXHIBITS

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[1] IPR2024-00009 (Dr. Reddy's Laboratories) and IPR2024-00107 (Sun Pharmaceutical Industries)has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.63(e), Petitioner submits the following current exhibit list.

EXHIBIT NO.	DESCRIPTION
1001	U.S. Patent No. 10,335,462
1002	Prosecution history excerpts for U.S. Patent No. 10,335,462
1003	Declaration of John Bantle, MD
1004	CV of John Bantle, MD
1005	Declaration of William J. Jusko, Ph.D.
1006	CV of William J. Jusko, Ph.D.
1007	Declaration of Paul Dalby, Ph.D.
1008	CV of Paul Dalby, Ph.D.
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1010	Intentionally Left Blank
1011	WO 2011/138421
1012	Lovshin, *Incretin-Based Therapies for Type 2 Diabetes Mellitus*, 5 NATURE REV. ENDOCRINOLOGY 262 (2009)
1013	Clinical Trial No. NCT00696657
1014	Clinical Trial No. NCT00851773
1015	WO 2006/097537
1016	U.S. Patent Application Pub. No. US2007/0010424
1017	U.S. Patent No. 5,512,549

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1018	Banting, *The Internal Secretion of the Pancreas,* 7 J. LAB. CLINICAL MED. 251 (1922)
1019	Bell, *Hamster Preproglucagon Contains the Sequence of Glucagon and Two Related Peptides*, 302 NATURE 716 (1983)
1020	Bydureon prescribing information (Jan. 2012)
1021	Byetta prescribing information (Oct. 2009)
1022	Drab, *Incretin-Based Therapies for Type 2 Diabetes Mellitus: Current Status and Future Prospects*, 30 PHARMACOTHERAPY 609 (2010)
1023	Drucker, *Enhancing Incretin Action for the Treatment of Type 2 Diabetes*, 26 DIABETES CARE 2929 (2003)
1024	Drucker, *The Incretin System: Glucagon-Like Peptide-1 Receptor Agonists and Dipeptidyl Peptidase-4 Inhibitors in Type 2 Diabetes*, 368 LANCET 1696 (2006)
1025	Glaesner, *Engineering and Characterization of the Long-Acting Glucagon-Like Peptide-1 Analogue LY2189265, an Fc Fusion Protein*, 26 DIABETES/METABOLISM RSCH. & REV. 287 (2010)
1026	HARRISON'S PRINCIPLES OF INTERNAL MED., Chapter 338 (Fauci et al. eds. 17th ed. 2008)
1027	Holst, *Truncated Glucagon-like Peptide I, an Insulin-Releasing Hormone from the Distal Gut*, 211 (2) FEBS LETTERS 169 (1987)
1028	Holst, *Glucagon-Like Peptide 1 and Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Type 2 Diabetes Mellitus*, 4 CURRENT OP. IN PHARMACOLOGY 589 (2004)
1029	Jimenez-Solem, *Dulaglutide, a Long-Acting GLP-1 Analog Fused with an Fc Antibody Fragment for the Potential Treatment of Type 2 Diabetes*, 12 CURRENT OP. IN MOLECULAR THERAPEUTICS 790 (2010)

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1030	Kim, *Effects of Once-Weekly Dosing of a Long-Acting Release Formulation of Exenatide on Glucose Control and Body Weight in Subjects with Type 2 Diabetes*, 30 DIABETES CARE 1487 (2007)
1031	Knudsen, *GLP-1 Derivatives as Novel Compounds for the Treatment of Type 2 Diabetes: Selection of NN2211 for Clinical Development*, 26 DRUGS OF THE FUTURE 677 (2001)
1032	Knudsen, *Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes*, 47 J. MED. CHEMISTRY 4128 (2004)
1033	Knudsen, *Liraglutide, a GLP-1 Analogue to Treat Diabetes*, *in* ANALOGUE-BASED DRUG DISCOVERY II (Fischer & Ganellin eds. 2010)
1034	U.S. Patent No. 6,268,343 ("Knudsen patent")
1035	Lund, *Emerging GLP-1 Receptor Agonists*, 16 EXPERT OP. ON EMERGING DRUGS 607 (2011)
1036	Mojsov, *Insulinotropin: Glucagon-like Peptide I (7-37) Co-encoded in the Glucagon Gene is a Potent Simulator of Insulin Release in the Perfused Rat Pancreas*, 79 J. CLINICAL INVESTIGATION 616 (1987)
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1039	*Victoza*, PHYSICIANS' DESK REFERENCE (65th ed. 2010)
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1043	U.S. Patent App. Pub. 2004/0102486
1044	Rohatagi, *Model-Based Development of a PPARγ Agonist, Rivoglitazone, to Aid Dose Selection and Optimize Clinical Trial Designs*, 48 J. CLINICAL PHARMACOLOGY 1420 (2008)
1045	Shargel, APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS (5th ed. 2005)
1046	Yun, *Pharmacokinetic and Pharmacodynamic Modelling of the Effects of Glimepiride on Insulin Secretion and Glucose Lowering in Healthy Humans*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 469 (2006)
1047	Tamimi, *Drug Development: From Concept to Marketing!*, 113 NEPHRON CLINICAL PRACTICE c125 (2009)
1048	FDA Guidance for Industry, *Exposure-Response Relationships - Study Design, Data, Analysis, and Regulatory Applications* (Apr. 2003)
1049	*International Conference on Harmonisation; Dose-Response Information to Support Drug Registration; Guideline; Availability*, 59 Fed. Reg. 55972 (Nov. 9, 1994) ("ICH 1994")
1050	Garber, *Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-Controlled, Dose-Response Trial*, 102 AM. J. MED. 491 (1997)
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1053	Møller, *Mechanism-Based Population Modelling for Assessment of L-Cell Function Based on Total GLP-1 Response Following an Oral Glucose Tolerance Test*, 38 J. PHARMACOKINETICS & PHARMACODYNAMICS 713 (2011)
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1055	Landersdorfer, *Mechanism-Based Population Modelling of the Effects of Vildagliptin on GLP-1, Glucose and Insulin in Patients with Type 2 Diabetes*, 73 BRIT. J. CLINICAL PHARMACOLOGY 373 (2011) "(Landersdorfer 2011b")
1056	U.S. Patent No. 5,118,666
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1058	Blonde, *Comparison of Liraglutide Versus Other Incretin-Related Anti-Hyperglycaemic Agents*, 14 (suppl. 2) DIABETES, OBESITY & METABOLISM 20 (2012)
1059	Murphy, *Review of the Safety and Efficacy of Exenatide Once Weekly for the Treatment of Type 2 Diabetes Mellitus*, 46 ANNALS OF PHARMACOTHERAPY 812 (2012)
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1071	U.S. Patent No. 6,284,727
1072	U.S. Patent No. 5,164,366
1073	U.S. Patent No. 6,458,924
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1075	U.S. Patent No. 7,022,674
1076	*ClinicalTrials.gov Background*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/about-site/background (last visited Mar. 10, 2023)

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1078	U.S. Patent App. Pub. No. 2004/0102486
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1081	Ozempic prescribing information (Oct. 2022)
1082	Scheduling Order, *Novo Nordisk Inc. v. Rio Biopharmaceuticals Inc.*, No. 22-294 (CFC) (D. Del. June 30, 2022), ECF No. 22
1083	Transfer Order, *In re: Ozempic (Semaglutide) Patent Litigation*, No. 3038 (MDL Aug. 5, 2022)
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1086	"Last Update Posted" definition from ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT00696657
1087	Prosecution history excerpts for U.S. Patent No. 9,764,003
1088	*Markman* Hearing Transcript, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del. July 13, 2023)
1089	Claim Construction Order, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del. July 25, 2023), ECF No. 148

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1090	Joint Claim Construction Brief, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del. May 1, 2023), ECF No. 119
1091	Declaration of Shannon M. Bloodworth in Support of Motion for *Pro Hac Vice* Admission of Shannon M. Bloodworth
1092	Declaration of David L. Anstaett in Support of Motion for *Pro Hac Vice* Admission of David L. Anstaett
1093	Declaration of Bryan D. Beel in Support of Motion for *Pro Hac Vice* Admission of Bryan D. Beel
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1096	Astrup, *Effects of Liraglutide in the Treatment of Obesity: A Randomised, Double-Blind, Placebo-Controlled Study*, 374 LANCET 1606 (2009)
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1099	Garber, *Long-Acting Glucagon-Like Peptide 1 Receptor Agonists*, 34 DIABETES CARE S279 (2011)
1100	Jose, *Exenatide Once Weekly: Clinical Outcomes and Patient Satisfaction*, 4 PATIENT PREFERENCE & ADHERENCE 313 (2010)

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1101	Patent and Exclusivity List for: NDA No. N209637 (Semaglutide – Ozempic) in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (2024)
1102	Rubio-Herrera, *Impact of Treatment with GLP1 Receptor Agonists, Liraglutide 3.0 mg and Semaglutide 1.0 mg, While on a Waiting List for Bariatric Surgery*, 11 BIOMEDICINES 2785 (2023)
1103	Highlights of Prescribing Information: Saxenda, Rev. 12/2014
1104	Vahl, *Gut Peptides in the Treatment of Diabetes Mellitus*, 13 EXPERT OPINION ON INVESTIGATIONAL DRUGS 177 (2004)
1105	Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity entry for NDA No. N022341 (Liraglutide Recombinant (Victoza)) (2011)
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1108	White, *A Brief History of the Development of Diabetes Medications*, 27 DIABETES SPECTRUM 82 (2014)
1109	Grunberger, *Monotherapy with the Once-Weekly GLP-1 Analogue Dulaglutide for 12 Weeks in Patients with Type 2 Diabetes: Dose-Dependent Effects on Glycaemic Control in a Randomized, Double-Blind, Placebo-Controlled Study*, 29 DIABETIC MEDICINE 1260 (2012)
1110	Karagiannis, *Subcutaneously Administered Tirzepatide vs Semaglutide for Adults with Type 2 Diabetes: A Systematic Review and Network Meta-Analysis of Randomised Controlled Trials*, DIABETOLOGIA (published online Apr. 13, 2024)

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1112	Ostawal, *Clinical Effectiveness of Liraglutide in Type 2 Diabetes Treatment in the Real-World Setting: A Systematic Literature Review*, 7 DIABETES THERAPY 411 (2016)
1113	Skrivanek, *Dose-Finding Results in an Adaptive, Seamless, Randomized Trial of Once-Weekly Dulaglutide Combined with Metformin in Type 2 Diabetes Patients* (AWARD-5), 16 DIABETES OBESITY & METABOLISM 748 (2014)
1114	Buse, *Liraglutide Once a Day Versus Exenatide Twice a Day for Type 2 Diabetes: A 26-Week Randomised, Parallel-Group, Multinational, Open-Label Trial (LEAD-6)*, 374 LANCET 39 (2009)
1115	Centers for Disease Control and Prevention National Diabetes Statistics Report https://www.cdc.gov/diabetes/data/statistics-report/index.html (last accessed May 1, 2024
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1117	Applah, *My Best Friends Are Taking Ozempic. Can I Share My Disapproval?*, New York Times (June 28, 2023)
1118	Novo Nordisk Company Announcement: Financial report for the period 1 January 2018 to 31 March 2018 (dated May 2, 2018)
1119	Highlights of Prescribing Information: Trulicity, Rev. 9/2014
1120	Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity entry for NDA No. N206321 (Liraglutide Recombinant – Saxenda and Ozempic) (2018)
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1125	Pi-Sunyer, *A Randomized, Controlled Trial of 3.0 mg of Liraglutide in Weight Management*, 373 NEW ENG. J. MED. 11 (2015)
1126	Pratley, *One Year of Liraglutide Treatment Offers Sustained and More Effective Glycaemic Control and Weight Reduction Compared with Sitagliptin, Both in Combination with Metformin, in Patients with Type 2 Diabetes: A Randomised, Parallel-Group, Open-Label Trial*, 65 INT'L J. CLINICAL PRACTICE 397 (2011)
1127	Memorandum Order, *Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.*, No. 23-cv-00101 (D. Del. Mar. 25, 2024), ECF No. 126
1128	[Proposed] Claim Construction Order, *Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.*, No. 23-cv-00101 (D. Del. Dec. 15, 2023), ECF No. 79
1129	CECIL TEXTBOOK OF MEDICINE, Chapters 233 (Obesity) and 242 (Diabetes Mellitus) (Goldman et al. eds., 22nd ed. 2004)
1130	Novo Nordisk Annual Report 2011
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1132	Amori, *Efficacy and Safety of Incretin Therapy in Type 2 Diabetes*, 298 J. AM. MED. ASS'N 194 (2007)
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1137	Bhansali, *Historical Overview of Incretin Based Therapies*, 58 SUPPL. TO JAPI 10 (2010)
1138	Holst, *The Incretin Approach for Diabetes Treatment*, 53 DIABETES S197 (2004)
1139	Lorenz, *Recent Progress and Future Options in the Development of GLP-1 Receptor Agonsists for the Treatment of Diabesity*, 23 BIOORGANIC & MED. CHEM. LETTERS 4011 (2013)
1140	Deposition transcript of Robin S. Goland (Apr. 9, 2024)
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1144	Holz, *Glucagon-Like Peptide-1 Synthetic Analogs: New Therapeutic Agents for Use in the Treatment of Diabetes Mellitus*, 10 CURRENT MED. CHEMISTRY 2471 (2003)
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1148	Yu, *Antihypertensive Effect of Glucagon-Like Peptide 1 in Dahl Salt-Sensitive Rats*, 21 J. HYPERTENSION 1125 (2003)
1149	Gutzwiller, *Glucagon-Like Peptide 1 Induces Natriuresis in Healthy Subjects and in Insulin-Resistant Obese Men*, 89 J. CLININCAL ENDOCRINOLOGY & METABOLISM 3055 (2004)
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1151	Liu, *The Exenatide Analogue AC3174 Attenuates Hypertension, Insulin Resistance, and Renal Dysfunction in Dahl Salt-Sensitive Rats*, 9 CARDIOVASCULAR DIABETOLOGY 32 (2010)
1152	Kodera, *Glucagon-Like Peptide-1 Receptor Agonist Ameliorates Renal Injury Through its Anti-Inflammatory Action without Lowering Blood Glucose Level in a Rat Model of Type 1 Diabetes*, 54 DIABETOLOGIA 96 (2011)
1153	Edwards, *GLP-1: Target for a New Class of Antidiabetic Agents?*, 97 J. ROYAL SOC'Y MED. 270 (2004)
1154	Zepbound® Prescribing Information (rev. March 2024)
1155	Bode, *Patient-Reported Outcomes Following Treatment with the Human GLP-1 Analogue Liraglutide or Glimepiride in Monotherapy: Results from a Randomized Controlled Trial in Patients with Type 2 Diabetes*, 12 DIABETES, OBESITY & METAB. 604 (2010)

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1157	Davidson, *Mild Renal Impairment and the Efficacy and Safety of Liraglutide*, 17(3) ENDOCRINE PRACTICE 345 (2011)
1158	Press Release, *Semaglutide 1.0 mg Demonstrates 24% Reduction in the Risk of Kidney Disease-Related Events in People with Type 2 Diabetes and Chronic Kidney Disease in the FLOW Trial* (Mar. 5, 2024)
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1161	Zeeuw, *Proteinuria, a Target for Renoprotection in Patients With Type 2 Diabetic Nephropathy: Lessons From Renaal*, 65 KIDNEY INT'L 6 (2004)
1162	Rizzo, *Glucose Lowering and Anti-atherogenic Effects of Incretin-based Therapies: Glp-1 Analogues and Dpp-4-inhibitors*, 18 EXPERT OP. INVESTIGATIONAL DRUGS 1495 (2009)
1163	Gutzwiller, *Glucagon-Like Peptide-1 Is Involved in Sodium and Water Homeostasis in Humans*, 73 DIGESTION 2 (2006)
1164	Kanbay, *Effect of Tirzepatide on Blood Pressure and Lipids: a Meta-analysis of Randomized Controlled Trials*, 25 DIABETES OBESITY METABOLISM 3766–3778 (2023)
1165	Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity ADA 258-59 (41st ed. 2021)

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1166	Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity ADA 258-59 (42d ed. 2022)
1167	First Amended Complaint, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-1040 (D. Del. Mar. 21, 2023), ECF No. 84
1168	U.S. Patent No. 6,899,699
1169	U.S. Patent No. 8,684,969
1170	Correa, *Ownership of Knowledge – the Role of Patents in Pharmaceutical R&D*, 82 BULLETIN WHO 784 (2004)
1171	McDuff, *Thinking Economically About Commercial Success*, 9(4) LANDSLIDE 37(2017)
1172	Khan, *Prescriptions for Trendy Diabetes and Weight-Loss Drugs Increased Over 2,000% Since 2019*, KOMODO (Feb. 17, 2023)
1173	Gordon, *The Share of Ozempic Users with Diabetes has Decreased Over Time, Indicating Increased Off-label Use – HCCI*, HEALTH CARE COST INSTITUTE, https://healthcostinstitute.org/hcci-originals-dropdown/topics/diabetes-and-insulin/ozempic-users-with-diabetes-have-decreased-over-time-indicating-increased-off-label-use
1174	Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity, FDA.GOV, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity
1175	Frequently Asked Questions on Patents and Exclusivity, FDA.GOV, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity
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1178	Novo Nordisk Annual Report 2007
1179	Corr, *The Pathway from Idea to Regulatory Approval: Examples for Drug Development*, NIH
1180	David, *Commercial Success: Economic Principles Applied to Patent Litigation*, *in*, ECONOMIC DAMAGES IN INTELLECTUAL PROPERTY: A HANDS-ON GUIDE TO LITIGATION 159 (2006)
1181	*Type 2 Diabetes*, MEDLINE PLUS, https://medlineplus.gov/ency/article/000313.htm
1182	Ingram, *More than 4,000 ads for Ozempic-style Drugs Found Running on Instagram and Facebook*, NBC NEWS (June 15, 2023)
1183	U.S. Patent No. 7,762,994
1184	Trilliant Health, 2023 Trends Shaping the Health Economy
1185	*Ozempic Statistics and Trends in 2024*, TRACKDRUGS, https://trackdrugs.com/Ozempic-statistics
1186	Gilbert, *Prescriptions for Ozempic and Similar Drugs have Skyrocketed, Data Shows*, WASHINGTON POST (Sept. 27, 2023)
1187	U.S. Patent No. 8,579,869
1188	U.S. Patent No. 9,108,002
1189	Gilbert, *Insurers Clamping Down on Doctors who Prescribe Ozempic for Weight Loss*, WASHINGTON POST
1190	Novo Nordisk Q1 2022 Earnings Call Transcript (Apr. 29, 2022)
1191	U.S. Patent No. 9,457,154
1192	U.S. Patent No. 9,132,239

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1193	U.S. Patent No. 8,672,898
1194	U.S. Patent No. 8,920,383
1195	U.S. Patent No. 9,687,611
1196	U.S. Patent No. 9,616,180
1197	U.S. Patent No. 10,376,652
1198	U.S. Patent No. 11,097,063
1199	U.S. Patent No. 9,861,757
1200	U.S. Patent No. 9,775,953
1201	U.S. Patent No. 9,486,588
1202	U.S. Patent No. 11,446,443
1203	U.S. Patent No. 11,311,679
1204	U.S. Patent No. 10,220,155
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1207	Weintraub, *These 15 Metro Areas Saw Biggest Jumps in Ozempic Use. They Might not be Where you Expect.*, USA TODAY (Oct. 25, 2023)
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1302	Reply Declaration of Allen Spiegel, M.D.
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1304	Reply Declaration of Arthur Z. Schwartzbard, M.D.
1305	CV of Arthur Z. Schwartzbard, M.D.
1306	Reply Declaration of Steven Coca, D.O., M.S.
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1310	Transcript of April 4, 2024 Deposition of George Bakris, M.D.
1311	Transcript of March 14, 2024 Deposition of Anne Flint, Ph.D.
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1326	Defendants' Stipulation Regarding Invalidity Grounds for U.S. Patent No. 10,335,462, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del. Aug. 8, 2024), ECF No. 241
1327	Reply Memorandum in Support of Plaintiffs' Motion for Transfer of Action to the District of Delaware Pursuant to 28 U.S.C. § 1407 for Coordinated and Consolidated Pretrial Proceedings, *In re: Ozempic (Semaglutide) Patent Litigation*, No. 3038 (MDL June 7, 2022), ECF No. 21
1328	Correspondence from David Anstaett (June 20, 2024)

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1330	Defendants' Second Supplemental Invalidity Contentions, *In Re: Ozempic (Semaglutide) Patent Litigation*, No. 22-MD-3038 (D. Del. Jan. 12, 2024)
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Dated: August 16, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served a true and correct copy of the foregoing: UPDATED LIST OF PETITIONER'S EXHIBITS and Exhibits 1326-1333 by email to the electronic service addresses for Patent Owner and Petitioner in IPR2024-0009 and IPR2024-00107:

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