

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SUN PHARMACEUTICAL INDUSTRIES LTD.  
AND SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioners,

v.

NOVO NORDISK A/S,

Patent Owner.

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U.S. Patent No. 10,335,462 to Jensen  
Issue Date: July 2, 2019  
Title: Use of Long-Acting GLP-1 Peptides

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*Inter Partes* Review IPR2024-00107

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**PETITIONER'S UPDATED EXHIBIT LIST AS OF MAY 16, 2024**

## TABLE OF EXHIBITS

EXHIBIT	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.
1009	Intentionally Left Blank
1010	Intentionally Left Blank
1011	WO 2011/138421
1012	Lovshin, <i>Incretin-Based Therapies for Type 2 Diabetes Mellitus</i> , 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
1018	Banting, <i>The Internal Secretion of the Pancreas</i> , 7 J. LAB. CLINICAL MED. 251 (1922)

EXHIBIT	DESCRIPTION
1019	Bell, <i>Hamster Preproglucagon Contains the Sequence of Glucagon and Two Related Peptides</i> , 302 NATURE 716 (1983)
1020	Bydureon prescribing information (Jan. 2012)
1021	Byetta prescribing information (Oct. 2009)
1022	Drab, <i>Incretin-Based Therapies for Type 2 Diabetes Mellitus: Current Status and Future Prospects</i> , 30 PHARMACOTHERAPY 609 (2010)
1023	Drucker, <i>Enhancing Incretin Action for the Treatment of Type 2 Diabetes</i> , 26 DIABETES CARE 2929 (2003)
1024	Drucker, <i>The Incretin System: Glucagon-Like Peptide-1 Receptor Agonists and Dipeptidyl Peptidase-4 Inhibitors in Type 2 Diabetes</i> , 368 LANCET 1696 (2006)
1025	Glaesner, <i>Engineering and Characterization of the Long-Acting Glucagon-Like Peptide-1 Analogue LY2189265, an Fc Fusion Protein</i> , 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, <i>Truncated Glucagon-like Peptide I, an Insulin-Releasing Hormone from the Distal Gut</i> , 211 (2) FEBS LETTERS 169 (1987)
1028	Holst, <i>Glucagon-Like Peptide 1 and Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Type 2 Diabetes Mellitus</i> , 4 CURRENT OP. IN PHARMACOLOGY 589 (2004)
1029	Jimenez-Solem, <i>Dulaglutide, a Long-Acting GLP-1 Analog Fused with an Fc Antibody Fragment for the Potential Treatment of Type 2 Diabetes</i> , 12 CURRENT OP. IN MOLECULAR THERAPEUTICS 790 (2010)

EXHIBIT	DESCRIPTION
1030	Kim, <i>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</i> , 30 DIABETES CARE 1487 (2007)
1031	Knudsen, <i>GLP-1 Derivatives as Novel Compounds for the Treatment of Type 2 Diabetes: Selection of NN2211 for Clinical Development</i> , 26 DRUGS OF THE FUTURE 677 (2001)
1032	Knudsen, <i>Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes</i> , 47 J. MED. CHEMISTRY 4128 (2004)
1033	Knudsen, <i>Liraglutide, a GLP-1 Analogue to Treat Diabetes</i> , in ANALOGUE-BASED DRUG DISCOVERY II (Fischer & Ganellin eds. 2010)
1034	U.S. Patent No. 6,268,343 (“Knudsen patent”)
1035	Lund, <i>Emerging GLP-1 Receptor Agonists</i> , 16 EXPERT OP. ON EMERGING DRUGS 607 (2011)
1036	Mojsov, <i>Insulintropin: Glucagon-like Peptide I (7-37) Co-encoded in the Glucagon Gene is a Potent Simulator of Insulin Release in the Perfused Rat Pancreas</i> , 79 J. CLINICAL INVESTIGATION 616 (1987)
1037	Nielsen, <i>Pharmacology of Exenatide (Synthetic Exendin-4): A Potential Therapeutic for Improved Glycemic Control of Type 2 Diabetes</i> , 117 REGUL. PEPTIDES 77 (2004)
1038	Seino, <i>Dose-Dependent Improvement in Glycemia with Once-Daily Liraglutide without Hypoglycemia or Weight Gain: A Double-Blind, Randomized, Controlled Trial in Japanese Patients with Type 2 Diabetes</i> , 81 DIABETES RSCH. & CLINICAL PRACTICE 161 (2008)
1039	<i>Victoza</i> , PHYSICIANS’ DESK REFERENCE (65th ed. 2010)

EXHIBIT	DESCRIPTION
1040	Vilsbøll, <i>Glucagon-Like Peptide-1 and Diabetes Treatment</i> , 21 INT'L DIABETES MONITOR 1 (2009)
1041	WO 03/002136
1042	WO 91/11457
1043	U.S. Patent App. Pub. 2004/0102486
1044	Rohatagi, <i>Model-Based Development of a PPAR<math>\gamma</math> Agonist, Rivoglitazone, to Aid Dose Selection and Optimize Clinical Trial Designs</i> , 48 J. CLINICAL PHARMACOLOGY 1420 (2008)
1045	Shargel, APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS (5th ed. 2005)
1046	Yun, <i>Pharmacokinetic and Pharmacodynamic Modelling of the Effects of Glimepiride on Insulin Secretion and Glucose Lowering in Healthy Humans</i> , 31 J. CLINICAL PHARMACY & THERAPEUTICS 469 (2006)
1047	Tamimi, <i>Drug Development: From Concept to Marketing!</i> , 113 NEPHRON CLINICAL PRACTICE c125 (2009)
1048	FDA Guidance for Industry, <i>Exposure-Response Relationships - Study Design, Data, Analysis, and Regulatory Applications</i> (Apr. 2003)
1049	<i>International Conference on Harmonisation; Dose-Response Information to Support Drug Registration; Guideline; Availability</i> , 59 Fed. Reg. 55972 (Nov. 9, 1994) ("ICH 1994")
1050	Garber, <i>Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-Controlled, Dose-Response Trial</i> , 102 AM. J. MED. 491 (1997)
1051	Landersdorfer, <i>Pharmacokinetic/Pharmacodynamic Modelling in Diabetes Mellitus</i> , 47(7) CLINICAL PHARMACOKINETICS 417 (2008)

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