

Filed: March 19, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN INSTITUTIONAL LLC and PFIZER INC.,

Petitioners,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2020-00324¹
U.S. Patent No. 8,114,833

UPDATED LIST OF PETITIONERS' EXHIBITS

¹ IPR2020-01252 has been joined with this proceeding.

EXHIBIT NO.	DESCRIPTION
1001	U.S. Patent No. 8,114,833, <i>Propylene Glycol-Containing Peptide Formulations which Are Optimal for Production and for Use in Injection Devices</i> (filed May 17, 2006) (issued Feb. 14, 2012)
1002	Declaration of Laird Forrest, Ph.D.
1003	Prosecution history excerpts for U.S. Patent No. 8,114,833
1004	International Publication No. WO 03/002136, <i>Stable Formulation of Modified GLP-1</i> (published Jan. 9, 2003) (“Flink”)
1005	International Publication No. WO 2004/004781, <i>Liquid Formulations with High Concentration of Human Growth Hormone (hgh) Comprising 1,2-Propylene Glycol</i> (published Jan. 15, 2004) (“Betz”)
1006	U.S. Patent No. 6,268,343, <i>Derivatives of GLP-1 Analogs</i> (filed Feb. 26, 1999) (issued July 31, 2001)
1007	EP 0 923 950, <i>Liquid Agent for Contact Lens</i> (issued June 23, 1999)
1008	M. Powell et al., <i>Parenteral Peptide Formulations: Chemical and Physical Properties of Native Luteinizing Hormone-Releasing Hormone (LHRH) and Hydrophobic Analogues in Aqueous Solution</i> , 8(10) PHARM. RES. 1258 (1991)
1009	E. Epperson, <i>Mannitol Crystallization in Plastic Containers</i> , 35 AM. J. HOSP. PHARM. 1337 (1978)
1010	W. Griffin et al., <i>Polyhydric Alcohols</i> , in CRC HANDBOOK OF FOOD ADDITIVES 431 (Thomas E. Furia ed., 2d ed. 1972)
1011	J. Jacobs, <i>Factors Influencing Drug Stability in Intravenous Infusions</i> , 27 J. HOSP. PHARM. 341 (Dec. 1969)

EXHIBIT NO.	DESCRIPTION
1012	MODERN PHARMACEUTICS (Gilbert S. Banker et al. eds., 3d ed. 1996)
1013	REMINGTON'S PHARMACEUTICAL SCIENCES (18th ed. 1990)
1014	International Publication No. WO 03/072195, <i>Method for Administering GLP-1 Molecules</i> (published Sept. 4, 2003).
1015	INTENTIONALLY LEFT BLANK
1016	INTENTIONALLY LEFT BLANK
1017	U.S. Patent No. 8,759,291, <i>Methods of Treatment using Exendin Peptides or GLP-1 Peptides</i> (filed Apr. 5, 2011) (issued June 24, 2014)
1018	U.S. Patent Application Publication US 2005/0148497, <i>Method for Administering GLP-1 Molecules</i> (July 7, 2005)
1019	International Publication No. WO 95/22560 A1, <i>Pharmaceutical Formulations of CNTF</i> (published Aug. 24, 1995)
1020	U.S. Patent No. 6,458,924, <i>Derivatives of GLP-1 Analogs</i> (filed Sept. 16, 1999) (issued Oct. 1, 2002)
1021	International Publication No. WO 00/37098 A1, <i>Shelf-Stable Formulation of Glucagon-Like Peptide-1</i> (published June 29, 2000)
1022	Handbook of Pharmaceutical Excipients (3d ed. 2000)
1023	Handbook of Pharmaceutical Excipients (4th ed. 2003)
1024	<i>Akers, Formulation Development of Protein Dosage Forms in DEVELOPMENT AND MANUFACTURE OF PROTEIN PHARMACEUTICALS</i> (2002)

EXHIBIT NO.	DESCRIPTION
1025	International Patent Publication No. WO 1999/040788, <i>Inotropic and Diuretic Effects of Exendin and GLP-1</i> (published August 19, 1999)
1026	DEVELOPMENT OF BIOPHARMACEUTICAL PARENTERAL DOSAGE FORMS (John A. Bontempo ed., 1997)
1027	Gatlin, <i>Formulation and Administration Techniques to Minimize Injection Pain and Tissue Damage Associated with Parenteral Products</i> in INJECTABLE DRUG DEVELOPMENT (1999)
1028	A DICTIONARY OF CHEMISTRY (1996) (excerpts)
1029	FDA Guidance for Industry - Chemistry Manufacturing and Controls (2003)
1030	U.S. Patent No. 5,514,097, <i>Self Administered Injection Pen Apparatus and Method</i> (issued May 7, 1996)
1031	International Publication No. WO 93/19175, <i>Receptor for the Glucagon-Like-Peptide-1 (GLP-1)</i> (published Sept. 30, 1993)
1032	International Publication No. WO 99/43705, <i>N-Terminally Truncated GLP-1 Derivatives</i> (published Sept. 2, 1999)
1033	International Publication No. WO 99/43706, <i>Derivatives of GLP-1 Analogs</i> (published Sept. 2, 1999)
1034	International Publication No. WO 99/43707, <i>N-Terminally Modified GLP-1 Derivatives</i> (published Sept. 2, 1999)
1035	International Publication No. WO 98/08871, <i>GLP-1 Derivatives</i> (published Mar. 5, 1998)
1036	International Publication No. WO 02/46227, <i>GLP-1 Fusion Proteins</i> (published June 13, 2002)

EXHIBIT NO.	DESCRIPTION
1037	International Publication No. WO 99/43708, <i>GLP-1 Derivatives of GLP-1 and Exendin with Protracted Profile of Action</i> (published Sep. 2, 1999)
1038	International Publication No. WO 99/43341, <i>GLP-1 Derivatives with Helix-Content Exceeding 25%, Forming Partially Structured Micellar-like Aggregates</i> (published Sept. 2, 1999)
1039	International Publication No. WO 87/06941, <i>Insulinotropic Hormone</i> (published Nov. 19, 1987)
1040	International Publication No. WO 90/11296, <i>Insulinotropic Hormone</i> (published Oct. 4, 1990)
1041	International Publication No. WO 91/11457, <i>GLP-1 Analogs useful for Diabetes Treatment</i> (published Aug. 8, 1991)
1042	International Publication No. WO 98/43658, <i>Glucagon-Like Peptide-1 Analogs</i> (published Oct. 8, 1998)
1043	International Publication No. EP 0 708 179, <i>Glucagon-Like Insulinotropic Peptide Analogs, Compositions, and Methods of Use</i> (published Dec. 22, 2004)
1044	International Publication No. EP 0 699 686, <i>Biologically Active Fragments of Glucagon-Like Insulinotropic Peptide</i> (published Oct. 8, 2003)
1045	International Publication No. WO 01/98331, <i>Glucagon-Like Peptide-1 Analogs</i> (published Dec. 27, 2001)
1046	J. Sturis et al., <i>GLP-1 Derivative Liraglutide in Rats with β-cell Deficiencies: Influence of Metabolic State on β-cell Mass Dynamics</i> , 140 BRIT. J. PHARMACOLOGY 123 (2003)
1047	J. Fransson et al., <i>Local Tolerance of Subcutaneous Injections</i> , 48 J. PHARM. PHARMACOL. 1012 (1996)

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