

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN INSTITUTIONAL LLC,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

Case IPR2020-00324¹
Patent 8,114,833

PATENT OWNER'S UPDATED LIST OF EXHIBITS

¹ IPR2020-01252 has been joined with this proceeding.

EXHIBIT	DESCRIPTION
2001	Declaration of Ryan P. Johnson in Support of Patent Owner’s Motion for Admission <i>Pro Hac Vice</i> of Ryan P. Johnson Under 37 C.F.R. § 42.10(c)
2002	Declaration of Laura T. Moran in Support of Patent Owner’s Motion for Admission <i>Pro Hac Vice</i> of Laura T. Moran Under 37 C.F.R. § 42.10(c)
2003	Chien-Hua Niu, <i>FDA Perspective on Peptide Formulation and Stability Issues</i> , 87 J. PHARM. SCIENCES 1331 (1998) (“Niu”)
2004	C. Goolcharran, et al., <i>Chemical Pathways of Peptide and Protein Degradation</i> , in PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS 70 (Sven Frokjaer & Lars Hovgaard eds.,2000) (“Goolcharran”)
2005	Mark C. Manning et al., <i>Stability of Protein Pharmaceuticals</i> , 6 PHARM. RESEARCH 903 (1989) (“Manning”)
2006	R.W. Payne, et al., <i>Peptide Formulation: Challenges and Strategies</i> , INNOVATIONS PHARM. TECH. 64 (2009) (“Payne”)
2007	E.T. Kaiser et al., <i>Secondary structures of proteins and peptides in amphiphilic environments (A Review)</i> , 80 PROC. NATL. ACAD. SCI. USA 1137 (1983) (“Kaiser”)
2008	Dean K. Clodfelter et al., <i>Effects of Non-Covalent Self-Association on the Subcutaneous Absorption of a Therapeutic Peptide</i> , 15 PHARM. RES. 254 (1998) (“Clodfelter”)
2009	Eva Y. Chi et al., <i>Physical Stability of Proteins in Aqueous Solution: Mechanism and Driving Forces in Nonnative Protein Aggregation</i> , 20 PHARM. RESEARCH 1325 (2003) (“Chi”)
2010	U.S. Patent No. 5,932,547
2011	Lotte Knudsen, et al., <i>Potent Derivatives of Glucagon-like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration</i> , 43 J. MED. CHEM. 1664 (2000) (“Knudsen 2000”)
2012	U.S. Patent Application Publication No. 2002/0061838
2013	Humira® Package Insert (revised 01/2003)
2014	Norditropin® Approved Labeling (revised 05/2000)
2015	<i>United States Pharmacopeia and National Formulary (USP 26-NF 21) 2003</i> (“USP 2003”)
2016	Alfred Doenicke, et al., <i>Osmolalities of Propylene Glycol-Containing Drug Formulations for Parenteral Use. Should Propylene Glycol Be Used as a Solvent?</i> , 75 ANESTH. ANALG. 431

	(1992) (“Doenicke”)
2017	Joseph M. Catanzaro et al., <i>Propylene glycol dermatitis</i> , 24 J. AM. ACAD. DERMATOLOGY 90 (1991) (“Catanzaro”)
2018	Bahar Vardar et al., <i>Incidence of lipohypertrophy in diabetic patients and a study of influencing factors</i> , 77 DIABETES RESEARCH & CLINICAL PRAC. 231 (2007) (“Vardar”)
2019	Kenneth Strauss et al., <i>A pan-European epidemiologic study of insulin injection technique in patients with diabetes</i> , 19 PRACTICAL DIABETES INT’L 71 (2002) (“Strauss”)
2020	Omnitrope® Highlights of Prescribing Information (dated 06/2009)
2021	U.S. Food & Drug Admin., <i>New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2), Guidance for Industry</i> (Dec. 2018) (“FDA Draft Guidance”)
2022	Declaration of Peter M. Tessier, Ph.D. dated September 18, 2020 (Confidential – Protective Order Material)
2023	Declaration of Dorthe Kot Englund dated September 16, 2020 (Confidential – Protective Order Material)
2024	Declaration of Tina Bjeldskov Pedersen, Ph.D. dated September 17, 2020
2025	Declaration of David Nolan dated September 17, 2020
2026	Curriculum Vitae of Peter M. Tessier (dated 09/2020)
2027	Berge, S. M., et al. <i>Pharmaceutical salts</i> . 66 JOURNAL OF PHARMACEUTICAL SCIENCES, 1-19 (1977) (“Berge”)
2028	Bourne, E. J. <i>The polyhydric alcohols. Acyclic polyhydric alcohols</i> . 6 SPRINGER-VERLAG, 345-362 (1958)
2029	Chang, X., et al. <i>NMR studies of the aggregation of glucagon-like peptide-1: formation of a symmetric helical dimer</i> . 515 FEBS LETTERS, 165-170 (2002)
2030	Cornford, E. M. <i>Correlation between lipid partition coefficients and surface permeation in Schistosoma japonicum</i> . 64 THE JOURNAL OF MEMBRANE BIOLOGY, 217-224 (1982)
2031	Danielli, J. F. <i>Chapter VIII: Permeability to Non-Electrolytes</i> . CAMBRIDGE: UNIVERSITY PRESS, 80-104 (1952)
2032	Fort, F. L., et al. <i>Hemolysis study of aqueous polyethylene glycol 400, propylene glycol and ethanol combinations in vivo and in vitro</i> . 38 PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY, 82-87 (1984) (“Fort”)

2033	Hammarlund, E. R., & Pedersen-Bjergaard, K. <i>Hemolysis of erythrocytes in various iso-osmotic solutions</i> . 50 JOURNAL OF PHARMACEUTICAL SCIENCES, 24-30 (1961)
2034	Hutak, C. M., et al. <i>The use of cell lysis as an index of ocular irritation potential</i> . 5 JOURNAL OF TOXICOLOGY: CUTANEOUS AND OCULAR TOXICOLOGY, 143-161 (1986)
2035	Kim, Y., et al. <i>FT-IR and near-infrared FT-Raman studies of the secondary structure of insulinotropin in the solid state: α-helix to β-sheet conversion induced by phenol and/or by high shear force</i> . 83 JOURNAL OF PHARMACEUTICAL SCIENCES, 1175-1180 (1994) (“Kim”)
2036	Fu, R. C. C., et al. <i>The biocompatibility of parenteral vehicles—in vitro/in vivo screening comparison and the effect of excipients on hemolysis</i> . 41 PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY, 164-168 (1987) (“Fu”)
2037	Naccache, P., & Sha'afi, R. I. <i>Patterns of nonelectrolyte permeability in human red blood cell membrane</i> . 62 THE JOURNAL OF GENERAL PHYSIOLOGY, 714-736 (1973) (“Naccache”)
2038	Padrick, S. B., & Miranker, A. D. <i>Islet amyloid polypeptide: identification of long-range contacts and local order on the fibrillogenesis pathway</i> . 308 JOURNAL OF MOLECULAR BIOLOGY, 783-794 (2001)
2039	Patel, N., & Newsham, L. G., <i>Experiments in Physical Pharmacy. VI. Factors Influencing Erythrocyte Fragility and Isotonicity Determination</i> . 35 AMERICAN JOURNAL OF PHARMACEUTICAL EDUCATION, 1-7 (1971) (“Patel & Newsham”)
2040	Rowley, S. D. <i>Hematopoietic stem cell cryopreservation: a review of current techniques</i> . 1 JOURNAL OF HEMATOTHERAPY, 233-250 (1992)
2041	Schellekens, H. <i>Bioequivalence and the immunogenicity of biopharmaceuticals</i> . 1 NATURE REVIEWS DRUG DISCOVERY, 457-462 (2002) (“Schellekens”)
2042	Senderoff, R. I., et al. <i>Consideration of conformational transitions and racemization during process development of recombinant glucagon-like peptide-1</i> . 87 JOURNAL OF PHARMACEUTICAL SCIENCES, 183-189 (1998)
2043	Setnikar, I., & Temelcou, O. <i>Osmotic concentration and osmotic pressure in injectable solutions</i> . 48 JOURNAL OF THE AMERICAN PHARMACEUTICAL ASSOCIATION (SCIENTIFIC ED.), 628-630 (1959) (“Setnikar & Temelcou”)

2044	Stratton, L. P., et al. <i>Controlling deamidation rates in a model peptide: Effects of temperature, peptide concentration, and additives</i> . 90 JOURNAL OF PHARMACEUTICAL SCIENCES, 2141-2148 (2001)
2045	Sztein, J. M., et al. <i>Comparison of permeating and nonpermeating cryoprotectants for mouse sperm cryopreservation</i> . 42 CRYOBIOLOGY, 28-39 (2001) (“Sztein”)
2046	Thorens, B., & Waeber, G. <i>Glucagon-like peptide-I and the control of insulin secretion in the normal state and in NIDDM</i> . 42 DIABETES, 1219-1225 (1993)
2047	Yang, X., et al. <i>Subzero nonfreezing storage of the mammalian cardiac explant: I. Methanol, ethanol, ethylene glycol, and propylene glycol as colligative cryoprotectants</i> . 30 CRYOBIOLOGY, 366-375 (1993)
2048	Wolffenbuttel, B. H., & Graal, M. B. <i>New treatments for patients with type 2 diabetes mellitus</i> . 72 POSTGRADUATE MEDICAL JOURNAL, 657-662 (1996)
2049	Highlights of Prescribing Information, Revised 08/2020 (“Victoza [®] Prescribing Information”)
2050	Internal Novo Nordisk Report, dated December 3, 2001 (Confidential – Protective Order Material)
2051	Internal Novo Nordisk Email Chain, beginning December 19, 2001 and certified translation thereof (Confidential – Protective Order Material)
2052	Internal Novo Nordisk Report, dated December 19, 2001 and certified translation thereof (Confidential – Protective Order Material)
2053	Internal Novo Nordisk Protocol, dated January 22, 2002 and certified translation thereof (Confidential – Protective Order Material)
2054	De Vos, A. M., et al. <i>Human growth hormone and extracellular domain of its receptor: crystal structure of the complex</i> . 255 SCIENCE, 306-312 (1992)
2055	Internal Novo Nordisk Meeting Minutes, dated April 12, 2002 and certified translation thereof (Confidential – Protective Order Material)
2056	Internal Novo Nordisk Protocol, dated April 29, 2002 (Confidential – Protective Order Material)
2057	Internal Novo Nordisk Protocol, dated June 3, 2002 and certified translation thereof (Confidential – Protective Order Material)
2058	Internal Novo Nordisk Study Plan, dated June 5, 2002 and certified translation thereof (Confidential – Protective Order Material)
2059	Internal Novo Nordisk Memo, dated June 27, 2002 and certified translation thereof (Confidential – Protective Order Material)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.