

Filed: September 25, 2020

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 No. IPR2020-00324

U.S. Patent No. 8,114,833

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Institutional LLC (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Novo Nordisk A/S (“Patent Owner”) with the Patent Owner Preliminary Response in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five (5) business days of the Patent Owner Response filed by Patent Owner on September 18, 2020, Paper Nos. 20 (Confidential) and 22 (Redacted). Petitioner’s objections provide notice to Patent Owner that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’833 patent” means U.S. Patent No. 8,114,833. All objections under FRE 801-803 (hearsay) apply to the extent that Patent Owner relies on the exhibit identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are from Patent Owner’s exhibit list and are used for identification purposes only. The use of an exhibit description does not indicate that Petitioner agrees with that description or characterization of the document.

Petitioner objects to paragraphs in the Patent Owner Preliminary Response that

rely on exhibits objected to in this Petitioner's Objection to Evidence.

| Exhibit | Patent Owner's Description | Objection |
|---------|--|---------------------------------|
| 2022 | Declaration of Peter M. Tessier, Ph.D. dated September 18, 2020 (Confidential – Protective Order Material) | A, D, F, K, L, O, P, T |
| 2023 | Declaration of Dorthé Kot Engelund dated September 16, 2020 (Confidential – Protective Order Material) | A, D, F, K, L, Q, R, S, W, X |
| 2024 | Declaration of Tina Bjeldskov Pedersen, Ph.D. dated September 17, 2020 | A, D, F, K, L, Q, R, S, W, X |
| 2025 | Declaration of David Nolan dated September 17, 2020 | A, D, F, K, L, Q, R, S, U, W, X |
| 2026 | Curriculum Vitae of Peter M. Tessier (dated 09/2020) | A, B, G, K, L |
| 2027 | Berge, S. M., et al. <i>Pharmaceutical salts</i> . 66 JOURNAL OF PHARMACEUTICAL SCIENCES, 1-19 (1977) (“Berge”) | A, B, D, F, J, K, L, R |
| 2028 | Bourne, E. J. <i>The polyhydric alcohols. Acyclic polyhydric alcohols</i> . 6 SPRINGER-VERLAG, 345-362 (1958) | A, B, C, D, E, F, G, I, K, L, R |
| 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) | D, F, J, R |
| 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) | A, B, D, F, J, K, L, R |
| 2031 | Danielli, J. F. <i>Chapter VIII: Permeability to Non-Electrolytes</i> . CAMBRIDGE: UNIVERSITY PRESS, 80-104 (1952) | A, B, D, E, F, G, I, J, K, L, R |

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|---------|---|------------------------------|
| 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") | A, B, D, F, J, K, L, R |
| 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) | A, B, D, F, J, K, L, R |
| 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) | A, B, C, D, E, F, J, K, L, R |
| 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") | A, B, D, F, J, K, L, R |
| 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") | A, B, D, F, J, K, L, R |
| 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") | A, B, D, F, J, K, L, R |
| 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) | A, B, D, F, J, K, L, R |

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| 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") | A, B, C, D, E, F, J, K, L, R |
| 2040 | Rowley, S. D. <i>Hematopoietic stem cell cryopreservation: a review of current techniques.</i> 1 JOURNAL OF HEMATOTHERAPY, 233-250 (1992) | A, B, D, F, J, K, L, R |
| 2041 | Schellekens, H. <i>Bioequivalence and the immunogenicity of biopharmaceuticals.</i> 1 NATURE REVIEWS DRUG DISCOVERY, 457-462 (2002) ("Schellekens") | A, B, D, F, J, K, L, R |
| 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) | A, B, D, F, J, K, L, R |
| 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") | A, B, D, F, J, K, L, R |
| 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) | A, B, D, F, J, K, L, R |
| 2045 | Sztejn, J. M., et al. <i>Comparison of permeating and nonpermeating cryoprotectants for mouse sperm cryopreservation.</i> 42 CRYOBIOLOGY, 28-39 (2001) ("Sztejn") | A, B, D, F, J, K, L, R |
| 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) | A, B, D, F, J, K, L, R |

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