Filed: July 7, 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 ten (10) business days of the Institution Decision issued by the Board on June 23, 2020, Paper No. 12. 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
2003	Chien-Hua Niu, *FDA Perspective on Peptide Formulation and Stability Issues*, 87 J. PHARM. SCIENCES 1331 (1998)	A, B, D, F, J, K, L
2004	C. Goolcharran, et al., *Chemical Pathways of Peptide and Protein Degradation, in* PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS 70 (Sven Frokjaer & Lars Hovgaard eds., 2000)	A, B, D, F, G, J, K, L
2005	Mark C. Manning et al., *Stability of Protein Pharmaceuticals*, 6 PHARM. RESEARCH 903 (1989)	A, B, D, F, J, K, L
2006	R.W. Payne, et al., *Peptide Formulation: Challenges and Strategies*, INNOVATIONS PHARM. TECH. 64 (2009)	A, B, C, D, E, F, J, K, L
2007	E.T. Kaiser et al., *Secondary structures of proteins and peptides in amphiphilic environments (A Review),* 80 PROC. NATL. ACAD. SCI. 1137 (1983)	A, B, D, F, J, K, L
2008	Dean K. Clodfelter et al., *Effects of Non-Covalent Self-Association on the Subcutaneous Absorption of a Therapeutic Peptide*, 15 PHARM. RES. 254 (1998)	A, B, D, F, J, K, L
2009	Eva Y. Chi et al., *Physical Stability of Proteins in Aqueous Solution: Mechanism and Driving Forces in Nonnative Protein Aggregation*, 20 PHARM. RESEARCH 1325 (2003)	A, B, D, F, J, K, L
2010	U.S. Patent No. 5,932,547	A, B, D, F, J, K, L
2011	Lotte Knudsen, et al., *Potent Derivatives of Glucagon-like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration,* 43 J. MED. CHEM. 1664 (2000)	A, B, D, F, J, K, L
2012	U.S. Patent Application Publication No. 2002/0061838	A, B, D, F, J, K, L

Exhibit	Patent Owner's Description	Objection
2013	Humira® Package Insert (revised 01/2003)	A, B, C, D, F, J, K, L, M, N
2014	Norditropin® Approved Labeling (revised 05/2000)	A, B, C, D, F, J, K, L, M, N
2015	*United States Pharmacopeia and National Formulary* (USP 26-NF 21) 2003	A, B, D, F, G, I, J, N
2016	Alfred Doenicke, et al., *Osmolalities of Propylene Glycol Containing Drug Formulations for Parenteral Use. Should Propylene Glycol Be Used as a Solvent?*, 75 ANESTH. ANALG. 431 (1992)	A, B, D, F, J, K, L
2017	Joseph M. Catanzaro et al., *Propylene glycol dermatitis*, 24 J. AM. ACAD. DERMATOLOGY 90 (1991)	A, B, D, F, J, K, L
2018	Bahar Vardar et al., *Incidence of lipohypertrophy in diabetic patients and a study of influencing factors*, 77 DIABETES RESEARCH & CLINICAL PRAC. 231 (2007)	A, B, C, D, E, F, J, K, L
2019	Kenneth Strauss et al., *A pan-European epidemiologic study of insulin injection technique in patients with diabetes*, 19 PRACTICAL DIABETES INT'L 71 (2002)	A, B, D, F, J, K, L
2020	Omnitrope® Highlights of Prescribing Information (dated 06/2009)	A, B, C, D, E, F, J, K, L, N
2021	U.S. Food & Drug Admin., *New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2), Guidance for Industry* (Dec. 2018)	A, B, C, D, E, F, G, J, K, L, M

Objection Key:

A: FRE 801/802/803 (hearsay)

B: FRE 901/902 (lacking authentication)

C: FRE 402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '833 patent or the prior art status is not clear

D: FRE 402 (relevance) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods

E: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '833 patent or the prior art status is not clear

F: FRE 403 (confusing, waste of time) to the extent the document is relied upon for secondary considerations of nonobviousness, there is no nexus to the claimed compositions and methods

G: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document

H: FRE 1001-1003 (best evidence)

I: FRE 403, 901 (improper compilation)

J: FRE 403 (cumulative)

K: FRE 402 (relevance) the document is not relevant to any issue in the IPR proceeding

L: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding

M: FRE 702/703 to the extent that Patent Owner submits an Expert Declaration that improperly or unreasonably relies on the exhibit

N: FRE 1006 (improper summary)

O: 37 C.F.R. § 42.65 (fails to provide underlying facts or data on which opinion is based)

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