

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2023-00723

Patent No. 8,129,343

**DECLARATION OF PAUL DALBY, PH.D., IN SUPPORT OF PETITION
FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 8,129,343**

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TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent No. 8,129,343	'343 patent
U.S. Patent No. 7,022,674	'674 patent
Boylan, <i>Parenteral Products</i> , in MODERN PHARMACEUTICS (Gilbert S. Banker et al. eds., 3d ed. 1996)	Boylan
U.S. Patent No. 6,514,500	Bridon
Dong, <i>Glucagon-Like Peptide-1 Analogs with Significantly Improved in vivo Activity</i> , in PEPTIDES: THE WAVE OF THE FUTURE (Michal Lebl et al. eds., 2001)	Dong
WO 03/002136	Flink
Knudsen, <i>Potent Derivatives of Glucagon-Like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration</i> , 43(9) J. MED. CHEM. 1664 (2000)	Knudsen 2000
Knudsen, <i>GLP-1 Derivatives as Novel Compounds for the Treatment of Type 2 Diabetes: Selection of NN2211 for Clinical Development</i> , 26(7) DRUGS OF THE FUTURE (2001)	Knudsen 2001
Knudsen, <i>Glucagon-Like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes</i> , 47(17) J. MED. CHEM. 4128 (2004)	Knudsen 2004
U.S. Patent No. 6,268,343	Knudsen Patent
Rando, <i>Functional Incorporation of Synthetic Glycolipids into Cells</i> , 77(5) PROC. NATL. ACAD. SCI. USA 2510 (1980)	Rando
REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (Alfonso R. Gennaro ed., 20th ed. 2000)	Remington
WO 00/37098	WO098

1. My name is Paul Dalby, Ph.D. I have been retained by Mylan Pharmaceuticals Inc. (“Mylan”) to provide my expert opinions regarding the unpatentability of U.S. Patent No. 8,129,343 (“the ’343 patent”) (Ex. 1002). I understand that Mylan intends to petition for *inter partes* review (“IPR”) of the ’343 patent, which is assigned to Novo Nordisk A/S (“Patent Owner”). I also understand that, in the IPR petition, Mylan will request that the United States Patent and Trademark Office cancel claims 1-6 (“the challenged claims”) of the ’343 patent as unpatentable. I submit this expert declaration to address and support Mylan’s IPR petition for the ’343 patent.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience; Prior Testimony

2. I earned my doctorate at Cambridge University, UK, in 1998 where I studied protein folding mechanisms, using protein engineering to alter the relative stabilities of the native, denatured, intermediate and transition states, and evaluating the effects of a range of temperature, pH and presence of viscosity modifiers in the formulation. From 1998 to 2000, I was a postdoctoral fellow at the University of Pennsylvania, where I studied the relationship between protein structure, stability, and function through protein engineering and biophysical characterization, and also methods to improve stability and minimize aggregation in protein therapeutic formulations. In 2000, I was appointed Lecturer at University College London

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