IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE OZEMPIC (SEMAGLUTIDE) PATENT LITIGATION	C.A. No. 22-md-3038-CFC **CONFIDENTIAL**
NOVO NORDISK INC. AND NOVO NORDISK A/S, Plaintiffs/Counterclaim Defendants, v. RIO BIOPHARMACEUTICALS INC., et al., Defendants/Counterclaim Plaintiffs.	C.A. No. 22-294-CFC
NOVO NORDISK INC. AND NOVO NORDISK A/S, Plaintiffs/Counterclaim Defendants, v. MYLAN PHARMACEUTICALS INC., Defendants/Counterclaim Plaintiffs.	C.A. No. 22-cv-1040-CFC

Opening Expert Report of Dr. Paul Dalby
Regarding Invalidity of U.S. Patent No. 10,335,462

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TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent No. 5,164,366	'366 patent
U.S. Patent No. 10,335,462	'462 patent
U.S. Patent No. 7,022,674	'674 patent
U.S. Patent No. 6,284,727	'727 patent
U.S. Patent No. 8,114,833	'833 patent
U.S. Patent No. 6,458,924	'924 patent
Deposition of Christine Jensen, M.D., Ph.D. (Nov. 8, 2023)	Jensen Dep.
Knudsen, *Glucagon-Like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes*, 47 J. MED. CHEM. 4128 (2004)	Knudsen 2004
U.S. Patent No. 6,268,343	Knudsen patent
Lovshin, *Incretin-Based Therapies for Type 2 Diabetes Mellitus*, 5 NATURE REVIEWS ENDOCRINOLOGY 262 (2009)	Lovshin
Lund, *Emerging GLP-1 Receptor Agonists*, 16 EXPERT OPINION ON EMERGING DRUGS 607 (2011)	Lund
Madsbad et al., *An Overview of Once-Weekly Glucagon-Like Peptide-1 Receptor Agonists—Available Efficacy and Safety Data and Perspectives for the Future*, 13 DIABETES, OBESITY & METABOLISM, 394 (2011)	Madsbad 2011
Boylan, *Parenteral Products*, *in* MODERN PHARMACEUTICS (Gilbert S. Banker et al. eds., 3d ed. 1996)	Modern Pharmaceutics
Clinical Trial No. NCT00696657	NCT657
Ozempic prescribing information (Oct. 2022)	Ozempic label
REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (Alfonso R. Gennaro ed., 20th ed. 2000)	Remington
Victoza, PHYSICIANS' DESK REFERENCE (65th ed. 2010)	Victoza label
WO 00/37098	WO '098
WO 03/002136	WO '136
WO 2011/058193	WO '193

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TABLE OF ABBREVIATIONS
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Full Name of Cited Reference	Abbreviation
WO 2011/073328	WO ’328
WO 2011/138421	WO ’421
WO 2006/097537	WO ’537

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1. My name is Paul Dalby, Ph.D. I have been retained by Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("DRL"), Rio Biopharmaceuticals Inc. and EMS S/A (collectively "Rio"), Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively "Sun"), Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, (collectively "Zydus"), and Mylan Pharmaceuticals Inc. ("MPI") (collectively, "Defendants"). Defendants have asked me to provide my expert opinions regarding the invalidity of claims 4, 5, and 7 of U.S. Patent No. 10,335,462 ("'462 patent"). I understand Novo Nordisk, Inc. and Novo Nordisk A/S (collectively, "Plaintiffs" or "Novo") assert that Defendants infringe claims 1, 3, 4, 5, and 7 of the '462 patent ("the asserted claims"). Because claims 1 and 3 of the '462 patent relate only to subject matter outside my area of expertise, I have not been asked to opine on those claims. I therefore address only claims 4, 5, and 7 of the '462 patent, which relate to my technical area of expertise. I reserve the right to address the invalidity of any additional claims later asserted by Plaintiffs.

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

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I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: March 19, 2024 By: 

Dr. Paul Dalby

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