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 IPR2023-00724
Patent 10,335,462

EXPERT DECLARATION OF PATRICK J. SINKO, PH.D. IN SUPPORT OF PATENT OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 10,335,462

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C. Claim Construction 12
VI. OZEMPIC® PRACTICES CLAIMS 4-10 OF THE '462 PATENT 14
A. Claim 1: A method for treating type 2 diabetes, comprising administering semaglutide once weekly in an amount of 1.0 mg to a subject in need thereof. 14
B. Claim 2: The method according to claim 1, wherein the semaglutide is administered by parenteral administration. 15
C. Claim 3: The method according to claim 2, wherein the solution is administered by subcutaneous injection. 16
D. Claim 4: The method according to claim 1, wherein the semaglutide is administered in the form of an isotonic aqueous solution comprising phosphate buffer at a pH in the range of 7.0-9.0. 16
E. Claim 5: The method according to claim 4, wherein the solution further comprises propylene glycol and phenol. 18
F. Claim 6: The method according to claim 4, wherein the pH is 7.4. 19
G. Claim 7: The method according to claim 6, wherein the solution further comprises propylene glycol and phenol. 19
H. Claim 8: The method according to claim 4, wherein the phosphate buffer is a sodium dihydrogen phosphate buffer. 20
I. Claim 9: The method according to claim 1, wherein the semaglutide is administered by subcutaneous injection in the form of an isotonic aqueous solution comprising at a sodium dihydrogen phosphate buffer at a pH in the range of 7.0-9.0, and

wherein the solution further comprises propylene glycol and phenol. 21

J. Claim 10: The method according to claim 9, wherein the pH is 7.4. 23

VII. THE FORMULATION USED IN THE SUSTAIN 6 AND FLOW CLINICAL TRIALS PRACTICES CLAIMS 4-10 OF THE '462 PATENT 23

VIII. CONCLUSION 25

I, Patrick J. Sinko, hereby declare under penalty of perjury:

I. INTRODUCTION

1. I have been retained by Groombridge, Wu, Baughman & Stone LLP, on behalf of Novo Nordisk A/S ("Novo Nordisk") to provide assistance regarding U.S. Patent No. 10,335,462 ("the '462 patent"). Specifically, I have been asked to provide my opinions regarding the whether Ozempic® practices claims 1-10 of the '462 patent (the "Challenged Claims") and whether the formulation used in the SUSTAIN 6 and FLOW clinical trials practices claims 4-10. Except as otherwise indicated, I have personal knowledge of the facts and opinions set forth in this declaration. All statements herein made of my own knowledge are true and all statements made on information and belief are believed to be true. If called upon to do so, I would testify competently thereto.

2. I am being compensated for my time at a rate of $950 per hour. I will be reimbursed for any expenses that I incur during the course of this work. My compensation is not contingent upon the results of my study, the substance of my opinions, or the outcome of any proceeding involving the Challenged Claims. I have no financial interest in the outcome of this matter or in the pending litigations involving Novo Nordisk A/S and Novo Nordisk Inc.

3. Except as otherwise indicated, I have personal knowledge of the facts set forth in this Declaration. All statements herein made of my own knowledge are

true and all statements made on information and belief are believed to be true. If called upon to do so, I would testify competently thereto.

II. BACKGROUND AND QUALIFICATIONS

4. I offer statements and opinions on behalf of Novo Nordisk, generally regarding Novo Nordisk's commercial embodiment, Ozempic, formulations used in Novo Nordisk's clinical trials, and the understanding of a person of ordinary skill in the art as it relates to the Challenged Claims.

5. I am a Distinguished Professor of Pharmaceutics in the Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, where I was Chair of the Department of Pharmaceutics from 1998 to 2008. I also served as the Associate Vice President for Research at Rutgers from 2007 through 2019, where I provided executive-level oversight of Comparative Medicine Resources, Research Core Facilities, In Vivo Research Services, Biomedical Advisory Committees, and the Controlled Substances program for our three regional campuses. Since 2003, I have held the Parke-Davis Endowed Chair in Pharmaceutics and Drug Delivery at Rutgers.

6. I am currently the immediate past President and member of the Board of Directors of the American Association of Pharmaceutical Scientists ("AAPS"), a professional, scientific organization with approximately 8,000 individual members and over 12,000 actively participating stakeholders employed in academia, industry,

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