PUBLIC VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD.
Petitioner,

v.

NOVO NORDISK A/S
Patent Owner.

Case IPR2023-00724[1]
Patent 10,335,462

DECLARATION OF DEFOREST MCDUFF, Ph.D.

[1] IPR2024-00009 (Dr. Reddy's Laboratories) has been joined with this proceeding.

I, DeForest McDuff, Ph.D., declare as follows:

I. Introduction

A. Qualifications

1. I am an economist at Insight Economics with more than 15 years of experience in economic consulting, research, and education. I provide economic expertise as a consultant and expert witness in many areas, including economic harm (lost profits, actual harm, unjust enrichment, reasonable royalty, loss of value), intellectual property (patents, trademarks, trade secrets, copyright), antitrust (monopolization, price discrimination, tying, price fixing), competition (economic harm, market definition, unfair competition, false advertising), valuation, financial analysis, and other areas.

2. I have significant experience evaluating the economics of the pharmaceuticals industry. I have provided expert analysis and consulting in more than 75 cases involving pharmaceuticals and related products, including analysis of economic damages, competition, economic harm, secondary considerations, and other issues. I have evaluated a number of pharmaceutical product launches, both in a litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical topics as well.

3. I am an Assistant Teaching Professor in the Department of Economics at the University of North Carolina at Chapel Hill. I earned a Ph.D. in Economics

from Princeton University, where I received a National Science Foundation Graduate Research Fellowship for academic research in financial economics and applied microeconomics. I graduated summa cum laude with a B.A. in Economics and a B.S. in Mathematics from the University of Maryland. My curriculum vitae contains more details on my education, experience, and testimony.

B. Scope of Work

4. In connection with my work on this matter, Insight Economics has been retained by Perkins Coie LLP on behalf of Mylan Pharmaceuticals, Inc. ("Mylan" or "Petitioner").[2] For this declaration, I was asked to evaluate and respond to the Expert Declaration of Christopher A. Vellturo submitted on January 17, 2024 ("Vellturo Declaration") regarding the alleged commercial success of Ozempic, commercialized by Novo Nordisk A/S ("Novo Nordisk" or "Patent Owner"). Specifically, I have been asked to evaluate the Vellturo Declaration's claims of commercial success as they relate to U.S. Patent No. 10,335,462 ("the '462 Patent" or "patent-in-suit").[3] This declaration is a statement of my opinions and the basis and reasons for those opinions.

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[2] Insight Economics is being compensated at a rate of $950 per hour for my work and at lower rates for time spent by others on my team. The compensation of Insight Economics does not depend on the substance of my testimony or the outcome of this matter.

[3] EX2300: Vellturo Declaration.

II. Background

A. Novo Nordisk

5. Novo Nordisk is a global healthcare company headquartered in Denmark.[4] Novo Nordisk discovers and develops medicines for diabetes, obesity, rare diseases, cardiovascular disease, and emerging therapy areas.[5] Novo Nordisk A/S is the Danish parent company of the Novo Nordisk group of companies.[6]

B. Type 2 diabetes

6. Type 2 diabetes is a disease related to improper function of how the body utilizes insulin and metabolizes sugar.[7] Type 2 diabetes results in a build-up of sugar in the bloodstream and can cause heart disease, stroke, vision loss, kidney disease, sensory loss, amputation, and other life-threatening conditions.[8] Treatment for Type 2 diabetes includes healthy eating, regular exercise, blood sugar monitoring, and a variety of medicine options: alpha-glucosidase inhibitors, biguanides, bile acid sequestrants, DPP-4 inhibitors, GLP-1 agonists, meglitinides, SGLT2 inhibitors, sulfonylureas, thiazolidinediones, and insulin.[9]

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4 EX1177: Novo Nordisk, Annual Report 2023, at 6.
5 EX1177: Novo Nordisk, Annual Report 2023, at 6.
6 EX1177: Novo Nordisk, Annual Report 2023, at 81.
7 EX1181: Medline Plus, "Type 2 diabetes," 2/10/2023, https://medlineplus.gov/ency/article/000313.htm.
8 EX1181: Medline Plus, "Type 2 diabetes," 2/10/2023, https://medlineplus.gov/ency/article/000313.htm.
9 EX1181: Medline Plus, "Type 2 diabetes," 2/10/2023, https://medlineplus.gov/ency/article/000313.htm.

C. Ozempic

7. Ozempic is a glucagon-like peptide (GLP-1) receptor agonist manufactured by Novo Nordisk A/S and marketed in the U.S. by Novo Nordisk Inc.[10] Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.[11] Ozempic was approved by the FDA on December 5, 2017[12] and launched in the U.S. in February 2018.[13] Ozempic injections are available in single-patient-use pens that deliver 0.25 mg with a strength of 2 mg / 3 mL (0.68 mg/mL), 0.5 mg with a strength 2 mg / 3 mL (0.68

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10 EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 1 and 25.

11 EX2069: Ozempic label, 9/2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf, at 1.

12 EX2106: FDA, Ozempic NDA 209637 Approval Letter, 12/5/2017, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209637s000ltr.pdf.

13 EX2494: Novo Nordisk, "Company announcement Financial report for the period 1 January 2018 to 21 March 2018," 5/2/2018, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/quarterly_financial_reports/2018/20180502_Financial%20statement_Q1%202018_UK.pdf, at 8.

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