

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 No. IPR2023-00724¹

Patent No. 10,335,462

DECLARATION OF ARTHUR Z. SCHWARTZBARD, M.D., F.A.C.C.

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

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'462 patent (EX1001)	U.S. Patent No. 10,335,462
2008 Guidance (EX1259)	FDA, Guidance for Industry, Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes (Dec. 2008)
2018 Background (EX1260)	FDA Background Document, Endocrinologic and Metabolic Drugs Advisory Committee Meeting (Oct. 24-25, 2018)
Abdul-Ghani (EX2086)	Abdul-Ghani, M., <i>et al.</i> , Cardiovascular Disease and Type 2 Diabetes: Has the Dawn of a New Era Arrived?, <i>Diabetes Care</i> , 40:813-820 (2017).
ACC 2018 (EX2091)	Das, S.R., <i>et al.</i> , ACC Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes and Atherosclerotic Cardiovascular Disease, <i>J. Am. Coll. Cardiol.</i> , 72: 3200-3223 (2018)
ACC-2020 (EX2092)	Das, S.R., <i>et al.</i> , Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, <i>J. Am. Coll. Cardiol.</i> , 76: 1117-1145 (2020)
ADA-2010 (EX1272)	American Diabetes Association, <i>Standards of Medical Care in Diabetes - 2010</i> , 33 DIABETES CARE S11 (2010)
ADA-2022 (EX2087)	ADA Standards of Medical Care., Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes, <i>Diabetes Care</i> 45(Suppl. 1):S144–S175 (2022)
ADA-2024 (EX1122)	American Diabetes Association, <i>Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023</i> , 46 DIABETES CARE S140 (2023)
Arnett (EX1224)	Arnett, 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease, 140 CIRCULATION e596 (2019)

Abbreviation	Description
Astrup (EX1251)	Astrup, <i>Safety, tolerability and sustained weight loss over 2 years with the once-daily human GLP-1 analog, liraglutide</i> , INTL. J. OBESITY, 36, 843-854 (2012) (published online Aug. 16, 2012).
Baggio (EX1228)	Baggio, <i>Biology of Incretins: GLP-1 and GIP</i> , 132 GASTROENTEROLOGY 2131 (2007)
Ban (EX1233)	Ban, <i>Cardioprotective and Vasodilatory Actions of Glucagon-Like Peptide 1 Receptor Are Mediated Through Both Glucagon-Like Peptide 1 Receptor–Dependent and –Independent Pathways</i> , 117 CIRCULATION 2340 (2008)
Bhansali (EX1137)	Bhansali et al., <i>Historical Overview of Incretin Based Therapies</i> , 58 SUPPL. TO JAPI 10 (2010)
Bose (EX1231)	Bose, <i>Glucagon-like Peptide 1 Can Directly Protect the Heart Against Ischemia/Reperfusion Injury</i> , 54 DIABETES 146 (2005)
Braunwald's (EX1257)	<i>Diabetes and the Cardiovascular System</i> , in BRAUNWALD'S HEART DISEASE, A TEXTBOOK OF CARDIOVASCULAR MEDICINE, Chapter 31 (12th ed. 2022)
Bucher (EX1255)	Bucher, <i>The Results of Direct and Indirect Treatment Comparisons in Meta-Analysis of Randomized Controlled Trials</i> , 50(6) J. CLIN. EPIDEMIOL. 683 (1997)
Bydureon Label (Jan. 2012) (EX1020)	Bydureon prescribing information (Jan. 2012)
Carbone (EX1250)	Carbone, <i>The CANVAS Program: Implications of Canagliflozin on Reducing Cardiovascular Risk in Patients with Type 2 Diabetes Mellitus</i> , 18 CARDIOVASC DIABETOL 64 (2019)
Cecil (EX1129)	CECIL TEXTBOOK OF MEDICINE, Chapters 233 (Obesity) and 242 (Diabetes Mellitus) (Goldman et al. eds., 22nd ed. 2004)
CV	Cardiovascular

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