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.
IPR2023-00724 ¹
Patent 10,335,462 B2
Reply Declaration of Dr. Allen Spiegel

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



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	A. General deficiencies in the Goland Declaration's opinions		
		1. The Goland Declaration failed to compare the '462 patent's claimed semaglutide once weekly 1.0 mg dosing regimen to the closest prior art	
		2. The Goland Declaration failed to support much of its reasoning	
		3. The Goland Declaration erroneously suggested that the use of Ozempic® according to its label has a nexus with the '462 patent's claimed semaglutide once weekly 1.0 mg dosing regimen	
	B. consider	The Goland Declaration did not establish any secondary derations to support a finding of nonobviousness81	
		1. The Goland Declaration failed to establish with relevant evidence that the inventions claimed in the '462 patent yielded unexpected results	
		2. The Goland Declaration failed to establish with relevant evidence that the inventions claimed in the '462 patent satisfied a long-felt but unmet need in the art	
		3. The Goland Declaration failed to establish with relevant evidence that the inventions claimed in the '462 patent have been the subject of praise	
		4. The Goland Declaration failed to establish with relevant evidence that there was skepticism toward the inventions claimed in the '462 patent	
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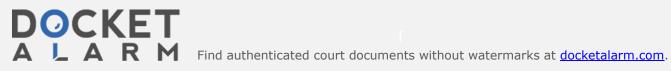


TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent No. 9,764,003	'003 patent (EX2002)
U.S. Patent No. 8,536,122	'122 patent (EX1067)
U.S. Patent No. 8,129,343	'343 patent (EX1068)
U.S. Patent No. 10,335,462	'462 patent (EX1001)
U.S. Patent No. 8,114,833	'833 patent (EX1121)
American Diabetes Association, <i>Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023</i> , 46 DIABETES CARE \$140 (2023)	ADA Standards 2023 (EX1122)
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Buse et al., Liraglutide Once a Day Versus Exenatide Twice a Day for Type 2 Diabetes: A 26-Week Randomised, Parallel-Group, Multinational, Open-Label Trial (LEAD-6), 374 LANCET 39 (2009)	Buse (EX1114)
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Centers for Disease Control and Prevention National Diabetes Statistics Report https://www.cdc.gov/diabetes/data/statistics-report/index.html (last accessed May 1, 2024)	CDC Report (EX1115)



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Garber et al., Liraglutide Versus Glimepiride Monotherapy for Type 2 Diabetes (LEAD-3 Mono): A Randomised, 52-Week, Phase III, Double-Blind, Parallel- Treatment Trial, 373 LANCET 473 (2009)	Garber 2009 (EX1097)				
Garber et al., Liraglutide, A Once-Daily Human Glucagon-Like Peptide 1 Analogue, Provides Sustained Improvements in Glycaemic Control and Weight for 2 Years as Monotherapy Compared with Glimepiride in Patients with Type 2 Diabetes, 13 DIABETES OBESITY & METABOLISM 348 (2011)	Garber 2011a (EX1098)				
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Transcript of the April 9, 2024 Deposition of Robin S. Goland, M.D.	Goland Dep. (EX1140)				
GRADE Research Study Group, <i>Glycemia Reduction in Type 2 Diabetes — Glycemic Outcomes</i> , 387 New Eng. J. MED. 1063 (2022)	GRADE (EX1124)				
Grunberger et al., Monotherapy with the Once-Weekly GLP-1 Analogue Dulaglutide for 12 Weeks in Patients with Type 2 Diabetes: Dose-Dependent Effects on Glycaemic Control in a Randomized, Double-Blind, Placebo-Controlled Study, 29 DIABETIC MEDICINE 1260 (2012)	Grunberger (EX1109)				



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