

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

PATENT OWNER'S RESPONSE

~~**PROTECTIVE ORDER MATERIAL**~~

~~**PROTECTIVE ORDER MATERIAL**~~

TABLE OF CONTENTS

I. Introduction	1
II. The Challenged Claims Are Directed to a Novel, Non-Obvious Invention	3
III. Asserted Art	5
A. WO421	5
B. Lovshin	6
C. '424 Publication	7
D. NCT657 (EX1013)	7
E. NCT773 (EX1014)	8
F. WO537	9
IV. Level Of Ordinary Skill	9
V. Claim Construction	10
VI. WO421 Is Not Prior Art to At Least '462 Claims 1-3	11
A. Legal Standards	11
B. WO421's §102(e) Date	13
C. Priority Date of '462 Claims 1-3	14
1. Conception	14
2. [REDACTED] [REDACTED]	17
VII. Grounds 1-2: Petitioner Fails to Show Anticipation	20
A. Ground 1 Fails	20
1. WO421's Disclosed Broad "Range" of Semaglutide Doses Does Not Anticipate	20
2. Petitioner Fails to Show WO421 Anticipates Claims 2-3	35
B. Ground 2 Fails	36
VIII. Grounds 3-5: Petitioner Fails to Show POSITA Would Have Been Motivated to Pursue the Claimed Method with REOS	41
A. Motivation to Combine	41

~~PROTECTIVE ORDER MATERIAL~~

B. REOS	46
1. POSITA Would Not Have “Optimized” and Selected a 1.0 mg Weekly Dose	47
2. Petitioner Fails to Show REOS That a 1.0 mg Weekly Dose Would Have Been Safe, Effective, and Tolerable	53
C. Ground 3 Fails	69
D. Ground 4 Fails	71
E. Ground 5 Fails	73
1. NCT773 Is Not Prior Art	73
2. Ground 5 Lacks Particularity	74
3. Ground 5 Does Not Render Obvious the Challenged Claims	75
F. Petitioner Fails to Address Objective Evidence of Non-Obviousness of Which Petitioner Is Aware	79
1. Nexus	80
2. Commercial Success	81
3. Unexpected Results	83
4. Long-Felt Need	87
5. Industry Praise	88
6. Skepticism	90
IX. Conclusion	90