

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 No. IPR2023-00724

Patent No. 10,335,462

**DECLARATION OF WILLIAM J. JUSKO, PH.D., IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,335,462**

TABLE OF CONTENTS

	Page
I. QUALIFICATIONS AND BACKGROUND	9
A. EDUCATION AND EXPERIENCE	9
B. PRIOR TESTIMONY	13
C. BASIS FOR OPINIONS AND MATERIALS CONSIDERED	14
D. RETENTION AND COMPENSATION	14
II. LEGAL STANDARDS.....	14
III. PERSON OF ORDINARY SKILL IN THE ART	17
IV. BRIEF SUMMARY OF OPINIONS.....	18
V. THE '462 PATENT [EX. 1001]	19
A. THE SPECIFICATION AND CLAIMS OF THE '462 PATENT	19
B. THE PROSECUTION HISTORY OF THE '462 PATENT.....	21
VI. CLAIM CONSTRUCTION.....	24
VII. BACKGROUND	26
A. PHARMACOKINETICS AND PHARMACODYNAMICS	26
B. DRUG DEVELOPMENT - CLINICAL TRIAL DESIGN	29
C. PHARMACOKINETICS AND PHARMACODYNAMICS RELATED TO GLP-1 AND SEMAGLUTIDE	36
1. GLP-1	36
2. GLP-1 derivatives	37
D. SEMAGLUTIDE CLINICAL TRIALS.....	45
VIII. SCOPE AND CONTENT OF THE PRIOR ART	49
A. WO421 [Ex. 1011].....	50
B. LOVSHIN [Ex. 1012]	52
C. WO537 [Ex. 1015].....	54
D. SEMAGLUTIDE CLINICAL TRIALS.....	56
1. NCT657 [Ex. 1013]	56
2. NCT773 [Ex. 1014]	58

TABLE OF CONTENTS
(continued)

	Page
3. Public Availability of ClinicalTrials.gov	60
E. KNUDSEN 2004 [EX. 1032]	67
F. LUND [EX. 1035].....	67
G. SEINO [EX. 1038]	71
H. VICTOZA LABEL [EX. 1039]	73
I. SHARGEL [EX. 1045].....	75
J. TAMIMI [EX. 1047].....	77
K. FDA EXPOSURE RESPONSE 2003 [EX. 1048]	79
L. ICH 1994 [EX. 1049]	80
M. KNUDSEN 2010B [EX. 1066].....	83
N. ADDITIONAL PRIOR ART AND REFERENCES	84
IX. UNPATENTABILITY OF THE '462 PATENT	84
A. GROUND 1: WO421 ANTICIPATED CLAIMS 1-3 OF THE '462 PATENT	84
1. Teachings of WO421	84
2. WO421 anticipated claim 1	84
3. WO421 anticipated claim 2	90
4. WO421 anticipated claim 3	90
B. GROUND 2: LOVSHIN ANTICIPATED CLAIMS 1-3 OF THE '462 PATENT.....	91
1. Teachings of Lovshin.....	91
2. Lovshin anticipated claim 1	91
3. Lovshin anticipated claim 2	94
4. Lovshin anticipated claim 3	95
C. GROUND 3: CLAIMS 1-10 OF THE '462 PATENT WOULD HAVE BEEN OBVIOUS OVER WO421	95
1. Claim 1 would have been obvious over WO '421	95
2. Claim 2 would have been obvious over WO '421	104
3. Claim 3 would have been obvious over WO '421	104

TABLE OF CONTENTS
(continued)

	Page
4. Claims 4-10 would have been obvious over WO '421 considering the '424 publication	105
D. GROUND 4: CLAIMS 1-10 OF THE '462 PATENT WOULD HAVE BEEN OBVIOUS OVER WO537 CONSIDERING LOVSHIN	105
1. Claim 1 would have been obvious over WO537 considering Lovshin	105
2. Claim 2 would have been obvious over WO537 considering Lovshin	114
3. Claim 3 would have been obvious over WO537 considering Lovshin	114
4. Claims 4-10 would have been obvious over WO537 considering Lovshin	115
E. GROUND 5: CLAIMS 1-10 OF THE '462 PATENT WOULD HAVE BEEN OBVIOUS OVER NCT657 AND NCT773.....	116
1. Claim 1 would have been obvious over NCT657 and NCT773	116
2. Claim 2 would have been obvious over NCT657 and NCT773	124
3. Claim 3 would have been obvious over NCT657 and NCT773	124
4. Claims 4-10 would have been obvious over NCT657, NCT773, and the '424 publication	125
F. NO SECONDARY CONSIDERATIONS OVERCOME <i>PRIMA FACIE</i> OBVIOUSNESS OF THE CLAIMED ALLEGED INVENTIONS.....	126
1. No unexpected results	126
2. No long-felt, unmet need or skepticism.....	126
X. CONCLUSION	127

TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent App. Pub. No. 2011/0166321	'321 publication
U.S. Patent App. Pub. No. US2007/0010424	'424 publication
U.S. Patent No. 10,335,462	'462 patent
U.S. Patent App. Pub. No. 2004/0102486	'486 publication
U.S. Patent No. 5,512,549	'549 patent
Bell, <i>Hamster Preproglucagon Contains the Sequence of Glucagon and Two Related Peptides</i> , 302 NATURE 716 (1983)	Bell
Blonde, <i>Comparison of Liraglutide Versus Other Incretin-Related Anti-Hyperglycaemic Agents</i> , 14 (suppl. 2) DIABETES, OBESITY & METABOLISM 20 (2012)	Blonde
Drab, <i>Incretin-Based Therapies for Type 2 Diabetes Mellitus: Current Status and Future Prospects</i> , 30 PHARMACOTHERAPY 609 (2010)	Drab
FDA Guidance for Industry, <i>Exposure-Response Relationships - Study Design, Data, Analysis, and Regulatory Applications</i> (Apr. 2003)	FDA Exposure Response 2003
Garber, <i>Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-Controlled, Dose-Response Trial</i> , 102 AM. J. MED. 491 (1997)	Garber
Holst, <i>Truncated Glucagon-like Peptide I, an Insulin-Releasing Hormone from the Distal Gut</i> , 211 (2) FEBS LETTERS 169 (1987)	Holst
<i>International Conference on Harmonisation; Dose-Response Information to Support Drug Registration; Guideline; Availability</i> , 59 Fed. Reg. 55972 (Nov. 9, 1994)	ICH 1994
Kirillova, <i>Results and Outcome Reporting in ClinicalTrials.gov, What Makes it Happen?</i> , 7(6) PLOS ONE 1 (2012)	Kirillova

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.