

TABLE OF CONTENTS

	Page
I. QUALIFICATIONS AND BACKGROUND.....	1
A. EDUCATION AND EXPERIENCE.....	1
B. PRIOR TESTIMONY.....	5
C. BASIS FOR OPINIONS AND MATERIALS CONSIDERED.....	6
D. RETENTION AND COMPENSATION.....	6
II. LEGAL STANDARDS.....	7
III. PERSON OF ORDINARY SKILL IN THE ART.....	9
IV. BRIEF SUMMARY OF OPINIONS.....	11
V. THE '462 PATENT.....	12
A. THE SPECIFICATION AND CLAIMS OF THE '462 PATENT.....	12
B. THE PROSECUTION HISTORY OF THE '462 PATENT.....	14
VI. CLAIM CONSTRUCTION.....	17
VII. BACKGROUND.....	18
A. PHARMACOKINETICS AND PHARMACODYNAMICS.....	18
B. DRUG DEVELOPMENT – CLINICAL TRIAL DESIGN.....	21
C. PHARMACOKINETICS AND PHARMACODYNAMICS RELATED TO GLP-1 AND SEMAGLUTIDE.....	27
1. GLP-1.....	28
2. GLP-1 derivatives.....	29
D. SEMAGLUTIDE CLINICAL TRIALS.....	36
VIII. SCOPE AND CONTENT OF THE PRIOR ART.....	41
A. WO '421.....	42
B. LOVSHIN 2009.....	45
C. WO '537.....	47
D. SEMAGLUTIDE CLINICAL TRIALS.....	49
1. NCT00696657.....	49
2. NCT00851773.....	51

TABLE OF CONTENTS
(continued)

	Page
3. Public Availability of ClinicalTrials.gov.....	54
E. KNUDSEN 2004.....	60
F. LUND.....	61
G. SEINO.....	65
H. VICTOZA LABEL.....	67
I. SHARGEL.....	69
J. TAMIMI.....	70
K. FDA EXPOSURE RESPONSE 2003.....	72
L. ICH 1994.....	74
M. KNUDSEN 2010B.....	77
N. BHANSALI.....	77
O. MADSBAD 2011.....	82
P. '833 PATENT.....	84
Q. ADDITIONAL PRIOR ART AND REFERENCES.....	85
IX. INVALIDITY OF THE '462 PATENT.....	86
A. CLAIMS 1 AND 3 OF THE '462 PATENT ARE ANTICIPATED BY WO '421, LOVSHIN 2009, OR NCT00696657.....	86
1. WO '421 Anticipated Claims 1 and 3 of the '462 Patent.....	86
2. Lovshin 2009 Anticipated Claims 1 and 3 of the '462 Patent.....	92
3. NCT00696657 Anticipated Claims 1 and 3 of the '462 Patent.....	97
B. CLAIMS 1, 3-5, AND 7 OF THE '462 PATENT WOULD HAVE BEEN OBVIOUS.....	101
1. Claims 1, 3-5, and 7 of the '462 Patent Would Have Been Obvious Over WO '421, NCT00696657, WO '537 and/or Lovshin 2009, Optionally in View of One or More of the '833 Patent and Madsbad 2011.....	101

TABLE OF CONTENTS
(continued)

	Page
2. Claims 1, 3-5, and 7 of the '462 Patent Would Have Been Obvious Over WO '421 Alone or in View of the '833 Patent.....	120
3. Claims 1, 3-5, and 7 of the '462 Patent Would Have Been Obvious Over WO '537 in View of Lovshin 2009.....	132
X. CONCLUSION.....	145

TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent App. Pub. No. 2011/0166321	'321 publication
U.S. Patent No. 10,335,462 (NN-OZEM-000000071-95)	'462 patent
Prosecution History for U.S. Patent No. 10,335,462 (NN-OZEM-000003820-4446)	'462 patent prosecution history
U.S. Patent App. Pub. No. 2004/0102486	'486 publication
U.S. Patent No. 5,512,549	'549 patent
U.S. Patent No. 8,114,833 (SEMA(JDG)_0000447-68)	'833 patent
Bell, <i>Hamster Preproglucagon Contains the Sequence of Glucagon and Two Related Peptides</i> , 302 NATURE 716 (1983)	Bell
Bhansali, <i>Historical Overview of Incretin Based Therapies</i> , 58 J. ASSOC. OF PHYSICIANS OF INDIA 10 (2010) (SEMA(JDG)_0000014-18)	Bhansali
Blonde, <i>Comparison of Liraglutide Versus Other Incretin-Related Anti-Hyperglycaemic Agents</i> , 14 (suppl. 2) DIABETES, OBESITY & METABOLISM 20 (2012)	Blonde
<i>ClinicalTrials.gov Background</i> , CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/about-site/background (last visited Mar. 15, 2024)	ClinicalTrials.gov Background
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

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.