UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD.
AND SUN PHARMACEUTICAL INDUSTRIES INC.

Petitioners,

v.

NOVO NORDISK A/S,
Patent Owner.

Case No. IPR2024-00107

Patent No. 10,335,462

**DECLARATION OF MELISSA E. WEINBERG, M.D.,
IN SUPPORT OF PETITION
FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 10,335,462**

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

Page

I. QUALIFICATIONS AND BACKGROUND 9

A. Education and Experience; Prior Testimony 9

B. Prior Testimony 10

C. Basis for Opinions and Materials Considered 10

D. Retention and Compensation 11

II. SUMMARY OF OPINIONS 11

III. LEGAL STANDARDS 13

IV. PERSON OF ORDINARY SKILL IN THE ART 14

V. THE '462 PATENT (EX. 1001) AND ITS CLAIMS 16

A. The '462 patent's claims 16

B. The Prosecution History of the '462 Patent 19

VI. CLAIM CONSTRUCTION 24

VII. BACKGROUND ON DIABETES AND THE USE OF GLP-1 DERIVATIVES FOR THE TREATMENT OF DIABETES 26

A. Diabetes Generally 26

B. Diabetes Treatment 27

C. The Use of GLP-1 Derivatives to Treat Diabetes 30

D. Use of Liraglutide to Treat Diabetes 32

E. Extended-Use GLP-1 Receptor Agonists 36

VIII. SCOPE AND CONTENT OF THE PRIOR ART 46

A. Lovshin (Ex. 1012) 47

B. U.S. Patent Application Pub. No. US2007/0010424 (Ex. 1016) 49

C. WO 2006/097537 (Ex. 1015) 54

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

D. WO 2011/138421 (Ex. 1011) 61

E. Semaglutide Clinical Trial Records 65

1. Clinical Trial No. NCT00696657 (Ex. 1013) 65

2. Clinical Trial No. NCT00851773 (Ex. 1014) 68

3. ClinicalTrials.gov is a Part of the POSA's Knowledge 70

F. Other Art that Informs the POSA's Knowledge 78

1. Drucker 2003 (Ex. 1023) 78

2. Holst 2004 (Ex. 1028) 79

3. Knudsen 2001 (Ex. 1031) 83

4. Knudsen 2004 (Ex. 1032) 87

5. Knudsen patent (U.S. Patent No. 6,268,343) (Ex. 1034) 93

6. Lund (Ex. 1035) 98

7. Victoza label (Ex. 1039) 98

8. WO 03/002136 (Ex. 1041) 102

9. Additional prior art and references 108

IX. UNPATENTABILITY OF THE CLAIMS OF THE '462 PATENT 108

A. Ground 1: WO421 Anticipated Claims 1–3 108

1. WO421 anticipated independent claim 1 108

2. WO421 anticipated claim 2 121

3. WO421 anticipated claim 3 123

B. Ground 2: Lovshin Anticipated Claims 1-3 124

1. Lovshin anticipated independent claim 1 125

2. Lovshin anticipated claim 2 131

3. Lovshin anticipated claim 3 132

C. Ground 3: Claims 1–10 of the '462 patent would have been obvious over WO421 alone or in view of the '424 publication 133

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

1. Claim 1 of the '462 patent would have been obvious over WO421 alone 133

2. Claims 2 and 3 of the '462 patent would have been obvious over WO421 alone 140

3. Claims 4–10 of the '462 patent would have been obvious over WO421 in view of the '424 publication 144

D. Ground 4: Claims 1–10 of the '462 patent would have been obvious over WO537 in view of Lovshin 144

1. Claim 1 of the '462 patent would have been obvious over WO537 in view of Lovshin 144

2. Claims 2 and 3 of the '462 patent would have been obvious over WO537 in view of Lovshin 153

3. Claims 4–10 of the '462 patent would have been obvious over WO537 in view of Lovshin 155

E. Ground 5: Claims 1–10 of the '462 patent would have been obvious over NCT657 in view of NCT773 and further in view of the '424 publication 155

1. Claim 1 of the '462 patent would have been obvious over NCT657 in view of NCT773 156

2. Claims 2 and 3 of the '462 patent would have been obvious over NCT657 in view of NCT773 172

3. Claims 4–10 of the '462 patent would have been obvious over NCT657 in view of NCT773 and further in view of the '424 publication 175

F. No Secondary Considerations Overcome Prima Facie Obviousness 175

1. No unexpected results 176

2. A POSA would have known there was no long-felt, unmet need for a once weekly GLP-1 receptor agonist or 1.0 mg dosing, nor was there any skepticism in the art 176

X. RESERVATION OF RIGHTS 176

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF ABBREVIATIONS

Full Name of Cited Reference	Abbreviation
U.S. Patent Application Pub. No. US2011/0166321	'321 publication
U.S. Patent Application Pub. No. US2007/0010424	'424 publication (Ex. 1016)
U.S. Patent No. 10,335,462	'462 patent (Ex. 1001)
U.S. Patent No. 10,335,462 file history excerpts	'462 file history (Ex. 1002)
U.S. Patent No. 5,512,549	'549 patent
Banting, *The Internal Secretion of the Pancreas*, 7 J. LAB. CLINICAL MED. 251 (1922)	Banting
Bell, *Hamster Preproglucagon Contains the Sequence of Glucagon and Two Related Peptides*, 302 NATURE 716 (1983)	Bell
Highlights of Prescribing Information: Bydureon, Revised: 01/2012	Bydureon label
Highlights of Prescribing Information: Byetta, Revised: 10/2009	Byetta label
ClinicalTrials.gov Background, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/about-site/background (last visited Mar. 10, 2023)	ClinicalTrials.gov Background
Drab, *Incretin-Based Therapies for Type 2 Diabetes Mellitus: Current Status and Future Prospects*, 30 PHARMACOTHERAPY 609 (2010)	Drab
Drucker, *Enhancing Incretin Action for the Treatment of Type 2 Diabetes*, 26 DIABETES CARE 2929 (2003)	Drucker 2003

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.