UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., Petitioner

v.

NOVO NORDISK A/S, PATENT OWNER

CASE IPR2024-00631 U.S. PATENT NO. 10,335,462 ISSUED: JULY 2, 2019

TITLE: USE OF LONG-ACTING GLP-1 PEPTIDES

DECLARATION OF JUDITH KORNER, M.D., Ph.D.

March 1, 2024



TABLE OF CONTENTS

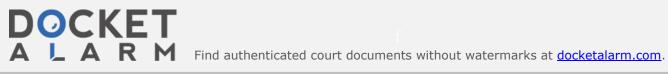
		<u> </u>	rage	
TAB	LE OF	F CONTENTS	i	
TAB	LE OI	ABBREVIATIONS	V	
I.	QUALIFICATIONS AND BACKGROUND			
	A.	Education and Experience	1	
	B.	Basis for Opinions and Materials Considered	4	
	C.	Retention and Compensation	4	
II.	SUM	MARY OF OPINIONS	5	
III.	LEG	AL STANDARDS	7	
IV.	PERS	SON OF ORDINARY SKILL IN THE ART	8	
V.	THE	'462 PATENT (Ex.1001) AND ITS CLAIMS	10	
VI.	CLA	IM CONSTRUCTION	16	
VII.	BACKGROUND ON DIABETES AND THE USE OF GLP-1 DERIVATIVES FOR THE TREATMENT OF DIABETES			
	A.	Diabetes Generally	18	
	B.	Diabetes Treatment	20	
	C.	The Use of GLP-1 Derivatives to Treat Diabetes	22	
	D.	Use of Liraglutide to Treat Diabetes	24	
	E.	Extended-Use GLP-1 Receptor Agonists	27	
VIII.	SCO	PE AND CONTENT OF THE PRIOR ART	36	
	A.	Lovshin (Ex.1012)	37	
	B.	U.S. Patent Application Pub. No. US2007/0010424 (Ex.1016)	39	
	C.	WO 2006/097537 (Ex.1015)	43	
	D.	WO 2011/138421 (Ex.1011)	48	
	E.	Semaglutide Clinical Trial Records	51	
		1. Clinical Trial No. NCT00696657 (Ex.1013)	51	
		2. Clinical Trial No. NCT00851773 (Ex.1014)	53	
		3. ClinicalTrials.gov is a Part of the POSA's Knowledge	55	



	F.	Othe	r Art tl	nat Informs the POSA's Knowledge	62
		1.	Druc	ker 2003 (Ex.1023)	62
		2.	Holst	2004 (Ex.1028)	63
		3.	Knuc	lsen 2001 (Ex.1031)	66
		4.	Knuc	lsen 2004 (Ex.1032)	70
		5.	Knuc	lsen patent (U.S. Patent No. 6,268,343) (Ex.1034)	74
		6.	Lund	(Ex.1035)	79
		7.	Victo	za label (Ex.1039)	79
		8.	WO	03/002136 (Ex.1041)	82
		9.	Addi	tional prior art and references	86
IX.				LITY OF THE CLAIMS OF THE '462	0=
				VO 401 A 1 01	
	A.			WO421 Anticipated Claims 1-3	
		1.		21 anticipated independent claim 1	
		2.		21 anticipated claim 2	
		3.		21 anticipated claim 3	
	В.	Grou		Lovshin Anticipated Claims 1-3	
		1.	Lovs	hin anticipated independent claim 1	
			a.	Lovshin disclosed the preamble of claim 1	103
			b.	Lovshin disclosed the element "comprising administering semaglutide"	104
			c.	Lovshin disclosed the element "once weekly in an amount of 1.0 mg"	105
			d.	Lovshin disclosed the element "to a subject in need thereof"	108
		2.	Lovs	hin anticipated claim 2	109
		3.	Lovs	hin anticipated claim 3	110
		4.		n 1 of the '462 patent would have been obvious over 21 alone	110



		a.	A skilled artisan would have been motivated to pursue the method recited in claim 1	111		
		b.	A skilled artisan would have had a reasonable expectation of success treating type 2 diabetes with a once weekly, 1.0 mg dose of semaglutide	115		
	5.		ns 2 and 3 of the '462 patent would have been ous over WO421 alone	118		
	6.		ns 4-10 of the '462 patent would have been obvious WO421 in view of the '424 publication	121		
C.	Ground 4: Claims 1-10 of the '462 patent would have been obvious over WO537 in view of Lovshin					
	1.		1 of the '462 patent would have been obvious over 37 in view of Lovshin	122		
		a.	A skilled artisan would have been motivated to pursue the method recited in claim 1	122		
		b.	A skilled artisan would have had a reasonable expectation of success treating type 2 diabetes with a once weekly, 1.0 mg dose of semaglutide	127		
	2.		ns 2 and 3 of the '462 patent would have been ous over WO537 in view of Lovshin	130		
	3.		ns 4-10 of the '462 patent would have been obvious WO537 in view of Lovshin	132		
D.	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					
	1.		n 1 of the '462 patent would have been obvious over 657 in view of NCT773	133		
		a.	A skilled artisan would have been motivated to pursue the method recited in claim 1	137		
		b.	A skilled artisan would have had a reasonable expectation of success treating type 2 diabetes with a once weekly. 1.0 mg dose of semaglutide	143		



X.	RES	ERVA	ATION OF RIGHTS	153
		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	153
		1.	No unexpected results	152
	Е.		econdary Considerations Overcome <i>Prima Facie</i> ousness	152
		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	151
		2.	Claims 2 and 3 of the '462 patent would have been obvious over NCT657 in view of NCT773	149



DOCKET A L A R M

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.

