

Filed: March 16, 2023

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. IPR2023-00723

Patent No. 8,129,343

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 8,129,343**

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Mandatory Notices.....	2
	A. Real Parties-In-Interest.....	2
	B. Related Matters.....	2
	C. Identification of Counsel (37 C.F.R. § 42.8(b)(3))	4
	D. Service Information (37 C.F.R. § 42.8(b)(4))	4
III.	Requirements for <i>Inter Partes</i> Review.....	5
	A. Grounds for Standing	5
	B. Identification of Challenge and Statement of Precise Relief Requested	5
IV.	Threshold Requirement for <i>Inter Partes</i> Review	6
V.	Statement of Reasons for the Relief Requested	6
	A. Summary of the Argument.....	6
	B. Level of Ordinary Skill in the Art.....	7
	C. The '343 Patent	9
	1. Disclosure.....	9
	2. Priority Date	10
	3. Claims	10
	4. Prosecution History.....	12
	D. Claim Construction (37 C.F.R. §§ 42.100(b), 42.104(b)(3))	13
	E. Scientific Background	14
	1. Diabetes.....	14
	2. GLP-1	14
	3. Peptide Synthesis and Structure Screening.....	16
	F. Scope and Content of the Prior Art	17
	1. Knudsen 2004 (Ex. 1010)	17
	2. The Knudsen Patent (Ex. 1012).....	19
	3. Dong (Ex. 1013).....	20

4.	Bridon (Ex. 1014)	21
5.	Knudsen 2001 (Ex. 1011)	22
G.	Legal Standard.....	24
H.	Ground 1: Knudsen 2004 in view of the Knudsen Patent, Dong, and Bridon (lead-compound framework).....	26
1.	Claims 1 and 4.....	26
2.	Claims 2 and 5.....	42
3.	Claims 3 and 6.....	44
I.	Ground 2: Knudsen 2001 in view of the Knudsen Patent, Dong, and Bridon (Lead-Compound Framework).....	44
1.	Claims 1 and 4.....	45
2.	Claims 2 and 5.....	50
3.	Claims 3 and 6.....	50
J.	Ground 3: Obviousness over the prior art and common drug development principles (under <i>KSR</i>)	51
1.	If applied as a rigid subject-matter-specific obviousness analysis, the lead-compound doctrine is inconsistent with <i>KSR</i>	51
2.	Under <i>Graham</i> and <i>KSR</i> , semaglutide would have been obvious because the differences between it and the closest prior art, liraglutide, involve predictable elements and tweaking result-effective variables	56
K.	Any Secondary Considerations Fail to Overcome Prima Facie Obviousness.....	59
1.	There were no unexpected or surprising results	60
2.	The prior art did not teach away from semaglutide.....	61
3.	There was no long-felt but unmet need	61
4.	Commercial sales do not save the '343 patent.....	61
5.	There was no industry skepticism.....	62
6.	Copying by generic drug makers is irrelevant.....	62
VI.	This Petition Should Not Be Denied Institution Under 35 U.S.C. § 325(d).....	63

A.	This Petition Presents Different Art And Arguments than Were Before The Examiner	64
B.	The Examiner Materially Erred.....	68
VII.	This Petition Should Not Be Denied Institution Under 35 U.S.C. § 314....	69
VIII.	Conclusion	70

TABLE OF AUTHORITIES

CASES

<i>10X Genomics, Inc. v. Bio-Rad Labs., Inc.,</i> IPR2021-00133, Paper 11 (PTAB May 14, 2021)	68
<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential)	64
<i>Altana Pharma AG v. Teva Pharms. USA, Inc.,</i> 566 F.3d 999 (Fed. Cir. 2009)	51
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential).....	69
<i>Aquestive Therapeutics, Inc. v. Neurelis, Inc.,</i> IPR2019-00451, Paper 8 (PTAB Aug. 13, 2019).....	68
<i>Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.,</i> 713 F.3d 1369 (Fed. Cir. 2013)	62
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential).....	63
<i>Daiichi Sankyo Co. v. Matrix Labs., Ltd.,</i> 619 F.3d 1346 (Fed. Cir. 2010)	24, 52
<i>Donner Tech., LLC v. Pro Stage Gear, LLC,</i> 979 F.3d 1353 (Fed. Cir. 2020)	54
<i>E.I. DuPont de Nemours & Co. v. Synvina C.V.,</i> 904 F.3d 996 (Fed. Cir. 2018)	25
<i>Eisai Co. v. Dr. Reddy's Labs., Ltd.,</i> 533 F.3d 1353 (Fed. Cir. 2008)	25
<i>Galderma Labs., L.P. v. Tolmar, Inc.,</i> 737 F.3d 731 (Fed. Cir. 2013)	60
<i>Graham v. John Deere Co.,</i> 383 U.S. 1 (1966).....	31, 52, 56, 59

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.