

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

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

TABLE OF CONTENTS

A.	Ground 3 Does Not Justify Discretionary Denial	1
B.	The Prosecution History Does Not Justify Discretionary Denial	2

TABLE OF AUTHORITIES

CASES

<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	5
<i>GMG Prods. LLC v. Traeger Pellet Grills LLC,</i> PGR2019-00024, Paper 17 (PTAB July 17, 2019)	4
<i>Hum Indus. Tech., Inc. v. Amsted Rail Co.,</i> IPR2023-00539, Paper 10 (PTAB July 26, 2023).....	5
<i>Intel Corp. v. Koninklijke Philips N.V.,</i> IPR2021-00370, Paper 10 (PTAB July 6, 2021).....	4
<i>ShenZhen Apaltek Co. v. Asetek Danmark A/S,</i> IPR2022-01317, Paper 7 (PTAB Feb. 6, 2023).....	3
<i>Teradata Corp. v. SAP SE,</i> IPR2020-00943, Paper 12 (PTAB Nov. 25, 2020).....	3
<i>Thorne Rsch., Inc. v. Trs. of Dartmouth Coll.,</i> IPR2021-00491, Paper 18 (PTAB Aug. 12, 2021).....	3

OTHER AUTHORITIES

37 C.F.R. § 42.23(b)	2
MPEP 2131.02(I)	3
MPEP 2144.08	3

With the Board’s authorization, Petitioner submits this Reply to address two bases Patent Owner alleges justify denial of institution. Neither basis has merit.

A. Ground 3 does not justify discretionary denial

Patent Owner, citing the *title* of Ground 3, complains of “extraordinary vagueness” and insists with a straight face that it lacks “any meaningful opportunity to respond.” POPR 18. But Patent Owner *does* respond on the merits to Ground 3. *See* POPR 49-53. Ground 3 relies on the same prior art as Grounds 1 and 2, and provides specific prior-art and declaration citations for (1) the prior-art disclosures of the structural fragments of semaglutide and their properties and (2) a POSA’s motivation to combine those disclosures. The only difference is the analytical framework for a POSA’s motivation: while Grounds 1 and 2 apply the narrower lead-compound analysis, Ground 3 explains that a POSA would have been motivated to reach semaglutide from the same prior art applying broader obviousness principles—routine optimization of known result-effective variables—because that is how drug-discovery worked at the priority date.

In particular, Ground 3 explains that the three requisite modifications to liraglutide involved sites known to affect bioactivity in specific ways, that there was a limited range of realistic options, and that screening those options would have been a routine part of drug discovery. Pet. 56-59. Ground 3 explained with particularity (1) why the Aib⁸ modification would have been obvious, Pet. 57; (2) why the fatty

diacid modification would have been obvious, Pet. 57-58; and (3) why the di-AEEA spacer modification would have been obvious, Pet. 58-59. Although Patent Owner insists that the number of options was large and unpredictable, those are issues of fact for expert testimony and trial. Ground 3 also relies on the same prior art for each claim limitation as Grounds 1 and 2. *See* Pet. 17-24. The additional references Patent Owner complains of give context to show a POSA's skill level and background knowledge; they confirm the declarations are well-reasoned and the references are not used to show disclosures of the limitations. And although Patent Owner complains Petitioner is "empower[ed]" by Ground 3 "to argue whatever it wants throughout the remainder of this proceeding," that is hyperbole. The rules ensure Petitioner keeps to the Petition's framing. 37 C.F.R. § 42.23(b).

Patent Owner also insists Ground 3 merits denying the whole Petition. POPR 18. But its cases do not support such a draconian request. In *Adaptics*, *EnergySource*, *InVue*, *ADT*, *John Crane*, and *Sainty Sumex*, every obviousness ground was deficient in some way, and many involved a complete failure to explain, or they asserted legally impossible arguments like multi-reference anticipation. Nor is Ground 3 a "catch-all" like in many of those cases—it is a different motivation theory.

B. The prosecution history does not justify discretionary denial

Even if some art appeared during prosecution, as Patent Owner contends, that

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.