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. IPR2023-00722

Patent No. 8,536,122

PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

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 19. But Patent Owner *does* respond on the merits to Ground 3. *See* POPR 52-57. 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. 62-65. Ground 3 explained with particularity (1) why the Aib^8 modification would have been obvious, Pet. 62-63; (2) why the

fatty diacid modification would have been obvious, Pet. 62-63; and (3) why the di-AEEA spacer modification would have been obvious, Pet. 62, 64. 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. 19-26. 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 19. 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 in the prosecution of the '122 patent (or its '343

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