

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 IPR2023-00722
Patent 8,536,122

**PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107**

I. Ground 3’s Amorphous Catch-All Lacks the Required Particularity

The POPR doesn’t rest on Ground 3’s “*title*” (*cf.* R.1 (emph.orig.)¹); rather, it shows the Petition’s improper “catch-all” (*cf.* R.2) ground would require PO to “address whether each and every claim limitation is not only taught by *each*” mentioned reference, “but [also] by *each... in combination with one or more of the other[s]*.”² POPR.17. The Reply concedes that (at *minimum*) **all** of “the same prior art [from] Grounds 1 and 2” is in play (R.1), but never explains *how* or *why* the documents in those separate four-reference combinations with different base references would be combined, let alone how the Petition purportedly *identifies, limits, or applies* the “common drug development principles” Petitioner invokes as part of “Ground 3.”³ Pet.56. Nor does the Petition point to “specific prior-art and declaration citations” for that same Ground 1 and 2 art, as the Reply argues.⁴ R.1.

The Reply states, *e.g.*, that “Ground 3 explained with particularity (1) why

¹ Unless noted all emphases added, cites omitted, and abbreviations as in POPR.

² That PO “*does* respond” on *some* aspects (R.1) doesn’t make Ground 3 proper.

³ While the Reply now seeks to cast unspecified “additional references” as mere “background” (R.2), the Petition did not—and the Reply cannot provide a do-over.

⁴ Ground 3 invokes “Grounds 1 and 2” only **after** arguing “semaglutide [is] obvious,” and only to address “formulation and method of treatment...” Pet.65.

the Aib⁸ modification would have been obvious, Pet.62-63.” R.1. False. Those pages never cite Dong (EX1013)—required for Grounds 1 and 2 (*cf.* Pet.52)—and never refer back to Ground 1 or 2 for support. Thus, because it lacks substance the Petition in fact allows Petitioner to “argue whatever it wants.” *Cf.* R.2.

Petitioner’s di-AEEA argument belies the Reply’s new claim that “Ground 3 *relies on the same... art* as Grounds 1 and 2,” but with new motivation. R.1. While Grounds 1 and 2 rely on *Bridon* for the di-AEEA spacer (Pet.41-43), the Petition’s Ground 3 does *not* cite *Bridon* (other than for *background* along with other references) or Grounds 1 and 2. Pet.64. Instead, it cites Petitioner’s experts, *who rely on a host of different art* not identified in the Petition. Pet.64. For example, Petitioner cites “EX1020, ¶224,” and “EX1024 ¶¶83-87”—neither cite *Bridon*—and “EX1022, ¶148,” referring to 12 other paragraphs (“108-119”) that discuss numerous references disclosing PEG-like spacers (*e.g.*, EXS1029, 1041, 1019, 1014, 1033, 1012, 1043, 1044, 1034, 1045, & 1038). Even when discussing *Bridon* in ¶¶116-118, Petitioner’s expert argues it “was not alone in disclosing the use of an AEEA (or di-AEEA) spacer,” and proposes added references for that teaching. The Petition’s attempt to rely on all of this art belies the Reply’s attempts to rewrite and eliminate that now. And, as PO’s case confirms (POPR.16-17), Petitioner’s dump truck approach to Ground 3 fails the requirements of “particularity” and fairness, justifying full denial. *Adaptics*, 17 (“Board may consider whether a lack of

particularity as *to one or more* of the asserted grounds justifies denial of an entire petition.”); *see also Elk Eng’g Sdn. Bhd. v. Wilco Marsh Buggies & Draglines, Inc.*, IPR2020-00344, Pap.12, 17-22 (Mar. 4, 2021) (denying rehearing where petitioner’s four grounds (of 20) lacked particularity and “infected the entire” petition).

II. Petitioner Confirms 325(d) Denial Is Warranted

AB part one. Petitioner’s “totality of the art” arguments (R.3; R.2 (“if *some* [of the] art appeared”)) ignore that every reference in Petitioner’s Grounds 1 and 2 was of record (Knudsen 2004 and the Knudsen Patent) or cumulative of references that were (Knudsen 2001, Bridon, and Dong). POPR.59-65. PO also showed Petitioner’s combinations and arguments are cumulative of the Examiner’s *arguments*, which first rejected the ’343 over the Knudsen Patent’s genus (which included liraglutide) and Larsen (a reference that disclosed Aib⁸), but then allowed the claims after PO limited them to semaglutide, despite having in hand a cumulative Bridon reference. Pet.61-62, 64-66. Thus, PO showed AB part one was doubly met—both substantially the same art *and* arguments were presented in prosecution.

Petitioner’s complaint now that the Examiner erred by applying a more *lenient* approach than the “lead-compound” analysis it complains of as presenting “a too-high burden” and “violat[ing]... *Graham* and *KSR*” (Pet.62; POPR.65-66) is, to begin with, not an AB part one issue: it is a (faulty) part two complaint that the Examiner—facing substantially the same art and arguments—did not make a

particular rejection. This is *not* error for part two. *E.g.*, *Ivantis*, IPR2022-01533, Pap.14; POPR.68; *cf.* R.5. It is also nonsensical (POPR.65-66), unsupported (Petitioner does not address details of the Examiner’s analysis, but instead concocts a non-existent “conce[ssion]” at POPR.65-66 (argument based on “Petitioner’s own reasoning”)), and conflicts with Petitioner’s own Ground 3 approach (R.1, 5).

Petitioner is incorrect that Knudsen 2001 and the Knudsen Patent are not cumulative. R.4; *cf.* POPR.62-63. But, even if true, Petitioner fails to address (and thus concedes) PO’s *separate* showing that Knudsen 2001 is cumulative of *Knudsen 2004*, “cited on” ’122’s face. POPR.62-63. Indeed, the POPR showed “Petitioner [] treats *Knudsen 2004* and *Knudsen 2001* as interchangeable with one another... by referring back to and relying on Ground 1’s *Knudsen 2004* arguments and reasoning as to *Knudsen 2001* in Ground 2 (Pet.50-56),” confirming Knudsen 2001 was cumulative of the art of record. POPR.63. Further, Petitioner’s *AB* part one argument that, even if Bridon is cumulative of *cited* art, “a reference *cited* but not previously *applied* should be given little weight” (R.4), tellingly rests on a pre-AB case. *AB* itself (like Petitioner’s *Intel* case (R.4)) makes clear part one is met if the art is cumulative of art of record, *whether discussed or not. AB*, 7-8.

Petitioner’s cases are inapposite. The *ShenZhen*, *Thorne Research*, and *Teradata* petitioners either presented (1) entire grounds or (2) primary references that were neither of record nor cumulative. Here, ***all*** of Petitioner’s references were of

record or cumulative. And *Intel*'s patent owner failed to "compare [the quotes] with Petitioner's [reference] citations" and shifted the burden to the Board to determine cumulativeness. *Intel Corp. v. Koninklijke Philips N.V.*, IPR2021-00370, Pap.10, 7-8 (July 6, 2021). But here, PO showed that the portions Petitioner and Examiner relied on overlapped. POPR.59-60. Indeed, Petitioner only tries to show Knudsen 2001 is non-cumulative (R.4), and, as explained above, fails.

AB part two. Despite its Reply, Petitioner *still* fails to show any error, positing only the Examiner's "fail[ure] to apply" Petitioner's combination in a wished-for rejection. R.5. But that is not error, and Petitioner's case does not support its assertion. POPR.67-69. *Hum*'s petitioner showed error because its new art taught "the very limitation... the examiner [found] to be missing from the prior art." *Hum Indus. Tech., Inc. v. Amsted Rail Co.*, IPR2023-00539, Pap.10, 52 (July 26, 2023). Unlike in *Hum*, Petitioner here identifies no evidence the Examiner "misapprehend[ed] or overlook[ed]" the art—it just asserts this *must* be so because Bridon was not applied in a rejection. R.5. But an examiner's "silence" in not making a desired rejection is not error. R.5; POPR.67-69; *Ivantis*, IPR2022-01533, Pap.14, 19; *AlmondNet*, IPR2022-01319, Pap.9, 11; *AB*, 8-9 ("If reasonable minds can disagree... it cannot be said that the Office erred").

Far from any error, Petitioner's Reply shows its Petition should be denied.

Respectfully submitted: /J. Steven Baughman/
J. Steven Baughman

August 17, 2023

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER'S SUR-
REPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY
RESPONSE UNDER 37 C.F.R. § 42.107 has been served in its entirety by causing
the aforementioned document to be electronically mailed to the following attorneys
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Dated: August 17, 2023

Respectfully submitted,

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