UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

Case IPR2022-00722
Patent 7,041,786

PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE (PAPER 6)
AND PETITIONER'S MOTION TO AMEND
REAL PARTY-IN-INTEREST STATEMENT[1]

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[1] This Paper was authorized by Board Order (Paper 12) on July 29, 2022.

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I. ANALYSIS OF §325(d) FAVORS INSTITUTION

The POPR exaggerates the relevance of the examination to the current grounds, misrepresents examiner findings, and overlooks substantial differences. Bausch concedes the petition presents a new reference (Li, EX1006) the Office never previously considered, in combination with Currie (EX1005), which the examiner never applied in any rejection. POPR, 4-5. Bausch argues the petition's asserted combination is cumulative to the examiner's assertion of Hidaka 1998 (EX2008) in an anticipation rejection and brief citation of Hidaka 2000 (EX2009) in a written description rejection. POPR, 30-36. But Bausch does not assert—nor could it—that the examiner ever issued ***any obviousness rejection***. Nor does Bausch identify any reliance by the examiner on disclosures comparable to the petition's Currie and Li combination to support modifying uroguanylin as part of an obviousness analysis. The examiner failed to recognize prior art disclosure of the proposed conservative substitution and never considered its unpredictability.

A. The Examiner Never Made Any Obviousness Rejection

The examiner's only rejections concerned an earlier version of claim 1 that permitted sequence variants of up to three residues, and only under §102 and §112. EX1004, 160-62, 172-73. Bausch amended claim 1 (*id*., 188) and argued that the amended claim was ***not anticipated*** because "Hikada [sic] teaches a peptide

sequence of uroguanylin 15 amino acids[2] in length where the residue at position 3 is an aspartic acid, but does not teach the peptide sequence of SEQ ID NO: 20." *Id.*, 192. The examiner allowed claim 1 without further rejection. *Id.*, 271-76. The examiner was unaware of any prior art teaching "a variant of uroguanylin having a glutamate residue at position 3, rather than the naturally occurring aspartate residue." EX1004, 173 (limited list of "pertinent" art). While Bausch misrepresents the examiner's §112 findings about the outer limits of Bausch's earlier and much broader claims as an obviousness determination (POPR, 34-36), the examiner never addressed predictability of the proposed ***conservative*** (i.e., very predictable) substitution supported by an analogous sequence identified in the art. EX1006, 53; EX1002, ¶123; *Advanced Bionics*, IPR2019-01469, Paper 6, at 8.

B. The Petition Presents New and Different Evidence

Bausch urges the Board to ratify the examiner's facially insufficient examination based on unsupported attorney argument, despite uncontroverted expert testimony. Critically, Bausch dismisses Li as cumulative despite Li's clear comparison and alignment of rat, opossum, and human uroguanylins—which suggest the conservative substitution proposed as ***obvious*** in Ground 1. POPR, 33-

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[2] Reference to "truncated" uroguanylin traces to ***Bausch***'s characterization of Hidaka 1998 during prosecution, despite Bausch's current position. POPR, 31 n.5.

34; Pet., 24-26 (Li shows the aspartic and glutamic acid residues in the second and third positions and identifies them as important for uroguanylin's desirable activity level); EX1006, 52-53 & FIG. 6; EX1002, ¶¶109, 121-124 (Li on positions 2 and 3); *id.*, ¶¶92-94, 120 (Currie on rat relevance). Li thus provides significant linking prior art context in Ground 1 that Hidaka 1998 lacked.

Bausch also contends Li is cumulative to Hidaka 2000 (EX2009), a portion of which the examiner cited in a written description rejection. POPR, 33-35 (arguing Fig. 1 "explicitly disclos[ed] rat uroguanylin's sequence."). But the examiner only cited Hidaka 2000 to establish that "a mutant peptide" in which the first two residues were deleted lacked the ability to form the correct disulfide pairing. EX1004, 164-65. Thus, the examiner concluded "the structural features of SEQ ID NO: 20 are not particularly representative of the claimed genus." *Id.* But no POSA would equate ***deleting the first two residues*** with using Li's naturally-occurring amino acid sequences (DE, ED, and DD) for positions 2 and 3. *E.g.*, Pet. 19, 25. Bausch identifies no evidence suggesting the examiner was aware of Li's prior art uroguanylin variant having a glutamate residue at position 3, let alone Li's alignment of the rat and human uroguanylin orthologs and disclosure, based on that alignment, of the importance of having acidic residues at positions 2-3. Record evidence supported by expert testimony, including prior art disclosure of the alignment/comparison, overcomes Bausch's unsupported attorney arguments.

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