REDACTED PUBLIC VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS INC.,
Petitioners,

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

Case IPR2022-00722[1]
Patent 7,041,786

PETITIONERS' REPLY TO PATENT OWNER RESPONSE

[1] IPR2023-00016 has been joined with this proceeding.

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I. INTRODUCTION

Making and using [Glu^3]-uroguanylin[2] would have been obvious before the critical date. Bausch's Patent Owner Response (POR) counters with legally- and factually-erroneous arguments. The legally-proper standard does not require proving uroguanylin was the only promising lead compound or Glu^3 was the only obvious substitution. Bausch also fails to show a POSA would have been "led away" from modifying uroguanylin; instead pursuing the toxic potency and pH insensitivity of the pathogenic, heat-stable *E. coli* enterotoxins (STs). Bausch's arguments ignore the literature and skill in the art, misconceive obviousness law, and thus should be rejected.

II. ARGUMENT

The POR presents no independent arguments against Grounds 2-4 (claims 2-6), instead they stand or fall with claim 1. POR, 67. Claim 1 recites a peptide consisting of amino-acid sequence SEQ ID NO: 20, which is [Glu^3]-uroguanylin. For claim 1, Bausch first argues a POSA would not have selected uroguanylin as lead compound because enterotoxins were more potent and interconverting topoisomers allegedly made uroguanylin unattractive. POR, i. Bausch next argues a POSA had no reason to substitute Asp^3 with Glu^3. POR, ii. Bausch last alleges

[2] Human unless otherwise indicated.

unexpected, superior results counter reasonable expectation of success. POR, iii. Each Bausch argument is wrong.

A. Bausch's Arguments Are Legally Erroneous.

Bausch implies claim 1 recites limitations (e.g., pathogenic potency or no topoisomerism) that are clearly absent. *E.g.*, POR, i-ii, 2, 26, 38 (arguing reasonable expectation of success required re same). Claim 1 merely recites [Glu^3]-uroguanylin peptide sequence, not any level of potency or topoisomerism. EX1063, ¶¶114-117; EX1060, 20:3-14 ("Claim 1 is for a peptide of the given sequence, and that's all"), 111:17-112:13, 108:22-110:15 (SEQ ID NO. 20 "just gives you the linear sequence"). Bausch's arguments are not commensurate with its claims.

Reasonable expectation of success is only required for what is claimed. *Intelligent Bio-Systems v. Illumina Cambridge*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Yet a POSA could make [Glu^3]-uroguanylin easily using known methods. *See, e.g.*, Pet., 21-22, EX1002, ¶¶66-67; Pet., 24, EX1002, ¶¶130-31; Pet., 35-36; EX1005, 3:8-45; EX1002, ¶¶130-31. This evidence is unrebutted. EX1060, 130:9-20, 126:10-128:4; EX1063, ¶¶8, 115. Bausch's reasonable-expectation arguments are wrong.

Bausch improperly requires a POSA to choose a synthetic enterotoxin over a synthetic uroguanylin, arguing a POSA would only maximize potency and

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