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

PETITIONER MYLAN'S REPLY SUPPORTING MYLAN'S MOTION TO EXCLUDE 37 C.F.R. §42.64(c)

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

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TABLE OF AUTHORITIES

I. INTRODUCTION

The Board should exclude Bausch EX2001-EX2007, EX2024, EX2025, EX2027, EX2028, and EX2040.

II. REASONS FOR RELIEF

A. EX2001-EX2007 – Fintiv Exhibits

Mylan moved for exclusion from formal consideration or, alternatively, for limitation of the exhibits to the forfeited purpose for which they were submitted. Paper 54 ("MtE"). Bausch does not respond. Paper 59 ("Opp.") passim.

B. EX2024 and EX2025 – Expert Declarations

Mylan moved to exclude Bausch's expert declarations for improper legal standards and misunderstanding the prior art. MtE 1-8. Bausch argues the motion improperly discusses the merits and its authority is distinguishable. Opp. 1-9. Bausch is wrong on both points. Showing how testimony is used improperly necessarily involves discussing how it was used and why it was improper.

Bausch argues *U.S. Gypsum v. Lafarge N. Am.,* 670 F.Supp.2d 737, 745 (N.D. Ill. 2009), is distinguishable. Opp. 3-4. Yet, as Mylan's motion showed, Bausch and its experts persist in pushing a discredited single-lead compound theory. MtE 2-3, citing EX2024, ¶¶92, 99, 141-41; EX2025, ¶¶64-73. Similarly, for reasonable expectation of success, Bausch requires "seeking to make a better anti-constipation drug," in an attempt to read in unclaimed features; yet claim 1 simply defines a sequence nearly identical to a natural ligand already identified for

treating constipation. The reasonable expectation of success inquiry is defined by what is claimed. *Intelligent Bio-Systems v. Illumina Cambridge*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (if not claimed, it is "of no moment" to REOS); *accord Institute Pasteur v. Focarino*, 738 F.3d 1337, 1348-49 (Fed. Cir. 2013) (remanding claims that did not "require" successful cleavage and break repair for consideration of other motivations for what was claimed). As *U.S. Gypsum* shows, expert testimony based on an improper legal standard should be excluded to create a clear record and discourage similar testimony in other cases.

Bausch accuses Mylan of "conflat[ing]… reasonable expectation of success and unexpected results." Opp. 5, citing MtE 5. Yet, in its reasonable expectation of success section, Bausch cites a decision on ***unexpected results***. *Genetics Institute v. Novartis Vaccines & Diagnostics,* 655 F.3d 1291, 1308 (Fed. Cir. 2011).

Bausch attempts to defend the experts' technical errors by changing the subject. Opp. 5-6, discussing MtE 5-6. Mylan's motion explained how Bausch's experts misunderstood Fig. 3 in Li (EX1006, 49), one of the principal grounds references, regarding relative potency. MtE 5. Bausch first mischaracterizes Li Fig. 3 as a comparison between different GCC ligands, Opp. 5-6, rather than as comparisons of pre- and post-incubation pairs of the same ligands. Next, Bausch changes the focus (Opp. 6) to Li's prediction that rat, human, and opossum uroguanylin would have similar affinities—a different point that supports Mylan's

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