

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 IPR2022-00722¹
Patent 7,041,786

SECOND DECLARATION OF BLAKE R. PETERSON, PH.D.

¹ IPR2023-00016 has been joined with this proceeding.

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I, Blake R. Peterson, declare as follows:

I. INTRODUCTION

1. I am the same Blake R. Peterson who previously filed a declaration (EX1002) in this proceeding. EX1002 contains the legal standards I was given to apply to this case, as well as my opinions regarding the level of skill of a person of ordinary skill in the art (POSA) and the obviousness of claims 1-6 of the '786 patent (7,041,786, EX1001) in view of the prior art. My qualifications are discussed in EX1002 as well as in my CV (EX1003). I also was deposed by attorneys for the Patent Owner (Bausch). EX2026.

2. I have been asked to review the declarations of Dr. Shailubhai (EX2023), Dr. Davies (EX2024), and Dr. Waldman (EX2025), and the materials they discussed. I have been asked to provide my opinions regarding those declarations and the materials they discussed from the perspective of a person of ordinary skill in the art. For purposes of my evaluation, I understand that the critical date for this patent is January 17, 2002. EX2024, ¶4. My opinions are based on my skills, knowledge, training, education, and experience, and my examination of the materials used in preparing this testimony, including the declarations and cited materials discussed above. I also have reviewed the transcripts of the depositions of Drs. Davies (EX1060), Shailubhai (EX1061), and Waldman (EX1062). My opinions are based on the current record, so I reserve the ability to

refine my opinions based on additional facts.

3. In summary, it is my opinion that a person of ordinary skill in the art at the critical date would have recognized that human uroguanylin was a most promising peptide for modification, and that a person of ordinary skill in the art would not have been dissuaded from selecting human uroguanylin for modification by the potency of ST enterotoxins or by topoisomeric conversion properties.

4. It is also my opinion that a person of ordinary skill in the art at the critical date would have been motivated to make [Glu³]-human uroguanylin for several reasons, discussed at length in my first declaration (EX1002). It is further my opinion that a person of ordinary skill in the art would not have been dissuaded from doing so in favor of making the peptide more like the ST enterotoxins, and none of the arguments presented by Drs. Davies or Waldman undermine the motivations for the modification discussed in my first declaration.

5. Furthermore, it is my opinion that the experimental data for human uroguanylin and [Glu³]-human uroguanylin discussed by Drs. Shailubhai, Davies, and Waldman do not demonstrate any unexpected, significant, and material improvement between the two compounds. They certainly do not demonstrate a difference in kind between the two compounds. Moreover, the data relate to only a portion of what is encompassed by the claims of the '786 patent and do not provide an apples-to-apples comparison of [Glu³]-human uroguanylin to the most similar

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