UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FLATWING PHARMACEUTICALS, LLC and
MYLAN PHARMACEUTICALS, INC.,
Petitioners,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case Nos. IPR2018-00168, -00169, -00170, and -00171[1]

U.S. Patent Nos. 9,549,938, 9,566,289, 9,566,290, and 9,572,823

**DECLARATION OF NARASIMHA MURTHY, PH.D
IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

[1] Case Nos. IPR2018-01358, -01359, -01360, and -01361 have been joined with these proceedings.

1. I, S. Narsimha Murthy, Ph.D., hereby declare that the following is true and correct. I previously provided a Declaration filed as Ex. 1005 in support of Paper #1, Petition for Inter Partes Review ("*Petition*"), and my testimony from that first Declaration remains the same. I am competent to make this Declaration based upon my personal knowledge and technical expertise, which I addressed in my first declaration.

2. A person of ordinary skill in the art ("POSA") would not have been surprised to learn that 5% by weight of tavaborole is an appropriate concentration in a topically applied composition for the treatment of onychomycosis. An active ingredient concentration of 5% by weight is well within the range of values that a person of ordinary skill in the art would have considered to be typical in view of the prior art.

3. *Austin* discloses ranges of tavaborole encompassing 5% as an effective biocide (Ex. 1007, *Austin* 9:5–9), as noted in my initial testimony, and as Dr. Lane agrees. [2] The ranges *Austin* discloses specifically include a 5% solution as

[2] *See* previous declaration testimony in IPR2018-00168 (Ex. 1005, ¶ 191; Ex. 2014, ¶ 58, 68 ("within a certain weight percent range encompassing the 5% w/w")), in IPR2018-00169 (Ex. 1005, ¶ 278; Ex. 2014, ¶ 61, 71), in IPR2018-

the endpoint of a preferred range of an effective anti-fungal. (Ex. 1007, *Austin* 9:5–9.)

4. The fact that *Austin* discloses a "preferably" broader range that encompasses 5%, and "especially" an intermediate range that specifically and explicitly recites 5% as an endpoint, and "more especially" a narrower range would not have discouraged a POSA from trying a 5% solution or in any manner taught away from a 5% solution.

5. Instead, the overlapping ranges in *Austin* that encompass and even expressly recite a 5% solution as an effective biocide would have encouraged a POSA to include that percentage solution in routine dose ranging studies. In light of *Austin* in combination with other references as explained in my initial testimony and the *Petition*, it would have been obvious to a POSA at the time of the alleged invention to try a 5% solution in routine dose ranging studies.

6. Dr. Lane testifies that *Austin* "is not directed to topical (or even pharmaceutical) compositions," but *Austin* includes disclosures (including those set forth in ¶¶ 7–9 *infra*) that, in combination with the other references cited, would suggest a topical pharmaceutical formulation to a POSA.

00170 (Ex. 1005, ¶ 143; Ex. 2014, ¶ 62, 72), and in IPR2018-00171 (Ex. 1005, ¶ 138; Ex. 2014, ¶ 56, 66).

7. *Austin* discloses that while tavaborole "may be used in undiluted form" it is "preferably formulated in a composition included a carrier" which "is generally selected so that the biocide composition is compatible with the medium to be selected." (Ex. 1007, *Austin* at 8:11–12, 24–25.) A POSA would understand from reading *Austin*, in combination with other references cited including *Brehove*, that a topical pharmaceutical formulation is an example such a "carrier" applied to the selected "medium" of the nail.

8. *Austin* further discloses:

> If the medium to be protected is an aqueous medium, the carrier is preferably water or a water-miscible organic solvent or mixture thereof. Examples of suitable water-miscible organic solvents are acetic acid, N,N-dimethylformamide, dimethylsulphoxide, N-methyl-2-pyrrolidine, alcohols such as ethanol or glycols such as ethylene glycol, propylene glycol and dipropylene glycol and lower C_{1-4}-alkyl carbitols such as methyl carbitol.

(Ex. 1007, *Austin* at 8:32–38.) Dr. Lane agrees that the nail is such an "aqueous environment" testifying that the "nail plate has been described as a hydrophilic gel membrane, or a hydrogel" and that "water content of the nail is an important factor in ensuring appropriate integrity and function of this tissue."[3] Dr. Reider agrees,

[3] *See* declaration testimony in IPR2018-00168 (Ex. 2014, ¶¶ 24 ("The water content of the nail is an important factor in ensuring appropriate integrity and

testifying that "[n]ail also contains a relatively high level of water content."[4] A POSA at the time of the alleged invention would have read these passages from *Austin*, in combination with the other references cites, as suggesting application to the nail with a reasonable expectation of success in the ranges disclosed, or at a minimum as providing a reasonable expectation of success in including the 5% solution disclosed in a routine dose ranging study.

9. I am informed that the Board has previously determined that "Austin is reasonably pertinent to the particular problem the inventors sought to solve" and "logically would have commended itself to the problem facing the inventors . . . ." (Ex. 1014 at 13, 14); that a POSA "would have had a reason to combine Austin and Brehove to reach the claimed invention with a reasonable expectation of success". (Ex. 1014 at 18, 21, 23; *see also*, Ex. 1014 at 28 (same finding for *Freeman*)) and "would have had a reasonable expectation that administering

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function of this tissue."), 48 ("the aqueous environment of the nail")), in IPR2018-00169 (Ex. 2014, ¶ 27, 51), in IPR2018-00170 (Ex. 2014, ¶ 28, 52), and in IPR2018-00171 (Ex. 2014, ¶ 22, 46).

[4] *See* declaration testimony in IPR2018-00168 (Ex. 2013, ¶ 41), in IPR2018-00169 (Ex. 2013, ¶ 44), in IPR2018-00170 (Ex. 2013, ¶ 45), and in IPR2018-00171 (Ex. 2013, ¶ 39).

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