UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ANACOR PHAMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2018-00169[1]
U.S. Patent No. 9,566,289

PATENT OWNER'S MOTION TO EXCLUDE

[1] Case No. IPR2018-01359 has been joined with this proceeding

Pursuant to 37 C.F.R. § 42.64, Patent Owner Anacor Pharmaceuticals, Inc. ("Anacor") moves to exclude Exhibit 1048 filed by Petitioner FlatWing Pharmaceuticals, LLC ("FlatWing"). Exhibit 1048 is the Declaration of Narasimha Murthy, Ph.D. in Support of Petitioner's Reply to Patent Owner's Reponse ("Murthy Reply Decl."). This motion preserves Anacor's objections to Dr. Murthy's reply declaration in Paper No 20.

Dr. Murthy's reply declaration should be excluded as exceeding the proper scope of reply evidence. "A reply may only respond to arguments raised in the . . . patent owner's response," 37 C.F.R. § 42.23(b), and "[r]eply evidence . . . must be responsive and not merely new evidence that could have been presented earlier," *The Scotts Co. v. Encap, LLC*, IPR2013-00110, Paper No. 37 at 2 (P.T.A.B. Dec. 11, 2013). These limits safeguard "the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim" in an *inter partes* review. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). Reply evidence that exceeds these limits is properly excluded in its entirety because "neither [the Federal Circuit] nor the Board must parse the reply [evidence] to determine which, if any parts . . . are responsive and which are improper." *Id*; *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, (Aug. 14, 2012) ("[I]ndications that a new issue has been raised in a reply include new evidence necessary to make out a

prima facie case [of] patentability or unpatentability . . . and new evidence that could have been presented in a prior filing.").

FlatWing's petition cited Samour (Ex. 1010) in combination with Austin (Ex. 1007) and Brehove (Ex. 1008) or Freeman (Ex. 1009) to establish the obviousness of claims 10 and 12–15 of U.S. Patent No. 9,566,289 ("the '289 patent"). Claims 10 and 12–15 recite a pharmaceutical formulation comprising tavaborole at "a concentration of about 5% w/w." In response to Anacor's evidence that the cited art teaches away from 5% w/w, FlatWing and Dr. Murthy have pivoted away from relying on Samour in favor of emphasizing overlapping ranges disclosed in the remaining references and arguing that a person of ordinary skill in the art ("POSA") would have arrived at 5% w/w through "routine" dose-ranging studies.

In pivoting away from Samour, Dr. Murthy newly opines, based on the overlapping ranges in the cited art, that "it would have been obvious to a POSA . . . to try the 5% solution in routine dose ranging studies" or that the ranges "provid[e] a reasonable expectation of success in including the 5% solution in a routine dose ranging study." *See* Murthy Reply Decl. (Ex. 1048) ¶¶ 2–5, 10, and 12. Despite acknowledging the overlapping ranges in his opening declaration, Dr. Murthy did not offer any of these opinions at that time, nor do these opinions respond to the opinions or analyses of Anacor's experts, specifically Dr. Lane's teaching-away

analysis or Dr. Reider's analysis of whether it would have been routine to perform dose-ranging studies with boron-containing compounds such as tavaborole. These opinions are also a departure from Dr. Murthy's original rationale that "a [POSA] would be motivated to substitute [tavaborole] . . . for the higher molecular weight compound disclosed in the Samour formulation to arrive at" the claimed invention. Murthy Decl. (Ex. 1005) ¶ 144; *see also id.* ¶ 146. Dr. Murthy's new "obvious . . . to try" opinion is also completely out of left field as FlatWing's petition does not rely on an obvious-to-try rationale with respect to the 5% w/w limitation. Dr. Murthy's new opinions exceed the scope of proper reply evidence.

Additionally Dr. Murthy's new opinions concerning Anacor's dose-ranging studies in Exhibit 1040 are untimely as Exhibit 1040 was known to FlatWing at the time it filed its petition. *See* Murthy Reply Decl. (Ex. 1048) ¶¶ 17–19. Exhibit 1040 was filed as an exhibit in IPR2018-00170 on November 21, 2017, and was in fact considered by Dr. Murthy to address limitations concerning tavaborole's mechanism of action in U.S. Patent No. 9,566,290. FlatWing and Dr. Murthy's belated analysis of Exhibit 1040 in support of their conclusory assertion that dose-ranging studies are "routine" is improper supplementation of FlatWing's petition for *inter partes* review, and is yet another reason why Dr. Murthy's reply declaration should be excluded.

CONCLUSION

For the foregoing reasons, Anacor respectfully requests that the Board exclude Dr. Murthy's reply declaration, Exhibit 1048.

Date: January 25, 2019

Respectfully submitted,

/s/ Aaron P. Maurer

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