

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ANACOR PHAMACEUTICALS, INC.,  
Patent Owner.

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Case No. IPR2018-00168<sup>1</sup>  
U.S. Patent No. 9,549,938

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**PATENT OWNER'S SURREPLY**

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<sup>1</sup> Case No. IPR2018-01358 has been joined with this proceeding

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**Rules:**

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There are two principal reasons why claims 3, 5, and 6 of U.S. Patent No. 9,549,938 (“the ’938 patent,” Ex. 1001) are patentable over the art cited by FlatWing and Mylan. *First*, as explained in Anacor’s Patent Owner’s Response, a person of ordinary skill in the art (“POSA”) in 2005 would have used a concentration of tavaborole higher than the 5% w/w recited in claims 3, 5, and 6 because the cited art teaches away from 5%. A POSA would have also expected tavaborole to have high keratin-binding affinity, a fact which would have led a POSA to a higher concentration in order to overcome the notoriously difficult challenge of delivering drugs through the human nail plate.

*Second*, Anacor’s evidence establishes that a POSA in 2005 would not have arrived at the recited concentration through routine experimentation, including “routine” dose-ranging studies, because the reactivity of boron-containing compounds such as a tavaborole would have been expected to render their formulation highly unpredictable—and thus far from routine. Indeed, the record in this case contains only two pre-priority formulations of boron-containing active ingredients—the formulation of a bortezomib prodrug in VELCADE<sup>®</sup> and Brehove’s formulation of the dioxaborinanes of Biobor JF<sup>®</sup>—and a POSA would have known both to suffer from significant stability problems.

Petitioners’ reply fails to rebut Anacor’s arguments and evidence.

Petitioners first erroneously suggest that the previous Board and Federal Circuit

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