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 No. IPR2018-00170
(Joined with IPR2018-01360)

U.S. Patent No. 9,566,290

PETITIONER'S REPLY TO PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE[1]

February 15, 2019

[1] Corresponding replies to Patent Owner's oppositions filed in related proceedings IPR2018-00168 (U.S. Patent No. 9,549,938, joined with IPR2018-01358), IPR2018-00169 (U.S. Patent No. 9,566,289, joined with IPR2018-01359), and IPR2018-00171 (U.S. Patent No. 9,572,823, joined with IPR2018-001361) are substantially the same as this reply, with citations adjusted to cite correctly the record in each proceeding.

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DISCUSSION

Petitioner's motion (*Petitioner's 37 C.F.R. § 42.64(c) Motion To Exclude*, Paper 29 (hereinafter "*Pet. Mot. Excl.*")) identified for every exhibit sought to be excluded the specific content that Patent Owner offered as hearsay testimony for the truth of the matter asserted. Patent Owner's opposition (Paper 31) did not respond to any of that, but instead merely asserts in conclusory fashion that its experts "cite to these publications as relevant evidence of the state of the art" (*Patent Owner's Opposition to Petitioner's Motion to Exclude* 2, Paper 31 (hereinafter "*PO Opp.*")), that they are "preexisting documentary evidence" (*id.* at 2), and that they "go to what a POSA would have known at the time of the invention" (*id.* at 4). But patent owner previously admitted that it cited scientific literature "after the priority date" (*Patent Owner's Response* 1, Paper 14 (hereinafter "*PO Resp.*")) about alleged "problems with transungual delivery" (*id.*). Exhibits 2004, 2005, 2006, 2008, 2015, 2016, 2026, 2028, 2035, and 2036 all purport to be dated ***after*** the asserted 2005 priority date of the patent in suit. They are ***not*** "preexisting documentary evidence" as Patent Owner claims (*PO Opp.* 2, Paper 31). They are not prior art disclosures independently operative in defining the state of the art as of the asserted 2005 priority date. Instead, Patent Owner relies on them for the truth of the opinions asserted by the authors in those articles, as identified in *Pet. Mot. Excl.* and below. Even for the other articles dated before

the priority date, Patent Owner did not use them to establish the state of the art but instead tried to use specific assertions in those articles for the truth of the matters asserted, as identified in *Pet. Mot. Excl.* and below.

Patent Owner and its experts repeatedly cite ***all*** of the exhibits to be excluded not for disclosures constituting the state of the art in 2005, but instead as supposed evidence demonstrating the truth of the matters asserted as opinions of the authors of those articles. As identified in *Pet. Mot. Excl.*, those matters asserted include: in Ex. 2004 that the nail is a "formidable barrier"; in Ex. 2005 about the supposed "inability to deliver a therapeutically effective amount"; in Ex. 2006 about supposed "poor drug diffusion into the highly keratinized nail plate and the long duration of treatment" (even though tavaborole itself also has a 48-week long treatment duration (Ex. 1042 at 2)); in Ex. 2007 that "topical therapy continues to pose a challenge"; in Ex. 2008 about "factors that could limit the accumulation and activity of drugs in the nail on topical application"; in Ex. 2009 for having been cited in Ex. 2007 about molecules larger than 300 Daltons facing hindrance in permeating the nail plate; in Ex. 2015 that VELCADE® was "the only boron-based therapeutic currently on the market" in 2009; in Ex. 2016 that the "ultimate fate of all boronic acids in air and aqueous media is their slow oxidation into boric acid"; in Exs. 2019 & 2020 about the alleged consequences of boron's ability to form complexes; in Exs. 2021, 2022, and 2023 about alleged consequences of boron's

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