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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 IPR2018-00169[1]
Patent 9,566,289 B2

Before GRACE KARAFFA OBERMANN, TINA E. HULSE, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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

I. INTRODUCTION

FlatWing Pharmaceuticals, LLC ("FlatWing") filed a Petition requesting an *inter partes* review of claims 1–15 of U.S. Patent No. 9,566,289 B2 (Ex. 1001, "the '289 patent"). Paper 1 ("Pet."). Anacor Pharmaceuticals, Inc. ("Patent Owner") did not file a Preliminary Response to the Petition. On June 8, 2018, we instituted an *inter partes* review of claims 1–15 of the '289 patent. Paper 9 ("Dec. Inst."), 16. On October 11, 2018, we granted Mylan Pharmaceuticals, Inc.'s (collectively with FlatWing, "Petitioners") Motion for Joinder (IPR2018-01359, Paper 3), and joined Case IPR2018-01359 with this proceeding. Paper 16.

Patent Owner filed a Response to the Petition. Paper 13 ("PO Resp."). Petitioners filed a Reply. Paper 19 ("Pet. Reply"). With our authorization, Patent Owner filed a Surreply. Paper 24 ("PO Surreply").

The parties also filed Motions to Exclude certain evidence. Paper 23 (Patent Owner's Motion); Paper 27 (Petitioners' Motion). The parties filed responsive papers to those motions. Paper 30 (Petitioners' Opposition to Patent Owner's Motion); Paper 33 (Patent Owner's Amended Reply to Petitioners' Opposition); Paper 29 (Patent Owner's Opposition to Petitioners' Motion); Paper 31 (Petitioners' Reply to Patent Owner's Opposition).

An oral hearing was held on March 1, 2019, a transcript of which has been entered in the record. Paper 34 ("Tr.").

We have authority under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine Petitioners have shown by a preponderance of the evidence that claims 1–15 of the '289 patent are unpatentable as obvious.

A. Related Proceedings

Petitioners filed three other petitions for *inter partes* review of related patents: U.S. Patent No. 9,549,938 (IPR2018-00168), U.S. Patent No. 9,566,290 (IPR2018-00170), and U.S. Patent No. 9,572,823 (IPR2018-00171). Paper 4, 2.

A fourth proceeding, Case IPR2015-01776, was filed by a different petitioner and is an *inter partes* review of U.S. Patent No. 7,582,621 ("the '621 patent"), which, according to Patent Owner, "asserts substantially the same claim of priority as U.S. Patent No. 9,566,289." *Id.* The Board there determined each of the claims of the '621 patent was unpatentable over the prior art. *Coalition for Affordable Drugs X LLC v. Anacor Pharms., Inc.*, Case IPR2015-01776, slip op. at 42 (PTAB Feb. 23, 2017) (Paper 70). The Federal Circuit affirmed the Board's final written decision as to claim 6 of the '621 patent (the only claim on appeal) in *Anacor Pharmaceuticals, Inc. v. Iancu*, 889 F.3d 1372, 1385 (Fed. Cir. 2018).

The parties also identify U.S. Patent Application Nos. 15/355,393 and 15/355,813 as administrative matters that may be affected by this proceeding. Pet. x; Paper 4, 2.

B. The '289 Patent

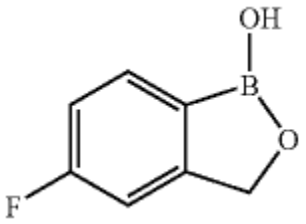
The '289 patent relates to boron-containing compounds useful for the topical treatment of onychomycosis and/or cutaneous fungal infections. Ex. 1001, Abstract. The claimed invention is directed to compounds that are active against fungi and have physiochemical properties that facilitate penetration of the nail plate. *Id.* According to the Specification, current

treatment for ungual and/or periungual infections generally falls into three categories: systemic administration of medicine; surgical removal of the nail or hoof followed by topical treatment of the exposed tissue; or topical application of medicine with bandages to keep the medication in place on the nail or hoof. *Id.* at 1:47–53.

Each of those approaches has major drawbacks. *Id.* at 1:53–54. Systemic administration of medicine typically requires long-term, high-dose therapy, which can have significant adverse effects on, for example, the liver and testosterone levels, which further negatively affects patient compliance. *Id.* at 1:58–2:8. Surgical treatment is painful and undesirable cosmetically (or not realistic for animals such as horses). *Id.* at 2:10–16. And topical dosage forms cannot keep the drug in contact with the infected area for therapeutically effective periods of time and, because of the composition of the nail, topical therapy for fungal infections have generally been ineffective. *Id.* at 2:17–41. Accordingly, the Specification states that "there is a need in the art for compounds which can effectively penetrate the nail. There is also need in the art for compounds which can effectively treat ungual and/or periungual infections." *Id.* at 2:66–3:2.

Dermatophytes are the most common cause of onychomycosis. *Id.* at 131:29–31. Onychomycosis caused by a dermatophyte is called *Tinea unguium*. *Id.* at 131:31–32. The most frequently isolated dermatophyte in *Tinea unguium* is *Trichophyton rubrum* (*T. rubrum*) followed by *Trichophyton mentagrophytes* (*T. mentagrophytes*). *Id.* at 131:32–33.

The ’289 patent claims a pharmaceutical formulation comprising 1,3-dihydro-5-fluoro-l-hydroxy-2, 1-benzoxaborole, which is referred to as compound 1 (*see id.* at 137:52–61) or compound C10 (*see id.* at 180:21) in the Specification, and has the chemical structure shown below.



C. Illustrative Claim

Petitioners challenge claims 1–15 of the ’289 patent, of which claims 1, 4, and 12 are independent claims. As explained further below, Patent Owner concedes that claims 1–9 and 11 are unpatentable, and contests only claims 10 and 12–15. Of the remaining claims, claim 12 is illustrative and is reproduced below:

> 12. A pharmaceutical formulation, comprising:
>
> about 5% w/w 1,3-dihydro-5-fluoro-l-hydroxy-2,1-benzoxaborole, or a pharmaceutically acceptable salt thereof;
>
> propylene glycol;
>
> ethanol; and
>
> ethylene diamine tetraacetic acid (EDTA) or a pharmaceutically acceptable salt thereof.

Ex. 1001, 324:12–19.

Claim 10 depends from claim 4 and further requires a 5% w/w concentration of 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole (referred to by the parties as “tavaborole” (Dec. Inst. 7)). *Id.* at

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