Trials@uspto.gov
571.272.7822

Paper No. 9
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FLATWING PHARMACEUTICALS, LLC,
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2018-00170
Patent 9,566,290 B2

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

HULSE, *Administrative Patent Judge*.

DECISION TO INSTITUTE
35 U.S.C. § 314(a)

I. INTRODUCTION

Flatwing Pharmaceuticals, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 9,566,290 B2 (Ex. 1001, "the '290 patent"). Paper 1 ("Pet."). Anacor Pharmaceuticals, Inc. ("Patent Owner") did not file a Preliminary Response to the Petition.

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the Petition, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of all claims and all grounds asserted in the Petition.

A. Related Proceedings

Petitioner has filed three other petitions for *inter partes* review of related patents: U.S. Patent No. 9,549,938 (IPR2018-00168), U.S. Patent No. 9,566,289 (IPR2018-00169), and U.S. Patent No. 9,572,823 (IPR2018-00171). Paper 4, 2.

Case IPR2015-01776 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. 9,566,290." *Id.* The Board 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 recently 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*, No. 2017-1947, 2018 WL 2187768, at *9 (Fed. Cir. May 14, 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. xi; Paper 4, 2.

B. The '290 Patent

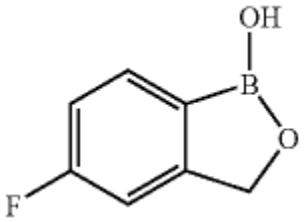
The '290 patent relates to boron-containing compounds useful for the topical treatment of onychomycosis and/or cutaneous fungal infections. Ex. 1001, Abstract. The claimed invention relates to compounds that are active against fungi and have physicochemical properties that facilitate penetration of the 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 1:52–58.

Each of the approaches has major drawbacks. *Id.* at 1:58–59. 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 1:63–2:7. Surgical treatment is painful and undesirable cosmetically (or not realistic for animals such as horses). *Id.* at 2:14–20. 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 2:21–45. 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 penetrate the nail . . . [and] effectively treat ungual and/or periungual infections." *Id.* at 3:3–7.

Dermatophytes are the most common cause of onychomycosis. *Id.* at 130:54–56. Onychomycosis caused by a dermatophyte is called *Tinea unguium*. *Id.* at 129:56–58. The most frequently isolated dermatophyte in *Tinea unguium* is *Trichophyton rubrum* followed by *T. mentagrophytes*. *Id.* at 130:58–59.

The '290 patent claims a method of treating onychomycosis of a toenail caused by *T. rubrum* or *T. mentagrophytes* by topically administering 1,3-dihydro-5-fluoro-l-hydroxy-2, 1-benzoxaborole, which is referred to as either compound 1 (*see id.* at 137:5–15) or compound C10 (*see id.* at 179:60) in the Specification, and has the following chemical structure:



C. Illustrative Claim

Petitioner challenges claims 1–12 of the '290 patent. Claim 1, the only independent claim, is illustrative and is reproduced below:

> 1. A method of treating a human having onychomycosis of a toenail caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, the method comprising:
>
> topically administering to the toenail a pharmaceutical composition comprising an amount of 1,3-dihydro-5-fluoro-l-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof, effective to inhibit an aminoacyl tRNA synthetase in the *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–12 of the '290 patent on the following grounds:

References	Basis	Claims challenged
Austin[1] and Brehove[2]	§ 103	1, 4, 7, 9, and 10
Austin, Brehove, and Samour[3]	§ 103	2, 3, 5, 6, 8, 11, and 12
Austin and Freeman[4]	§ 103	1, 4, 7, 9, and 10
Austin, Freeman, and Samour	§ 103	2, 3, 5, 6, 8, 11, and 12

Petitioner also relies on the Declarations of Stephen Kahl Ph.D. ("Kahl Decl.," Ex. 1003) and S. Narasimha Murthy Ph.D. ("Murthy Decl.," Ex. 1005).

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[1] Austin et al., WO 95/33754, published Dec. 14, 1995 ("Austin," Ex. 1007).
[2] Brehove, US 2002/0165121 A1, published Nov. 7, 2002 ("Brehove," Ex. 1008).
[3] Samour et al., US 6,224,887 B1, issued May 1, 2001 ("Samour," Ex. 1010).
[4] Freeman et al., WO 03/009689 A1, published Feb. 6, 2003 ("Freeman," Ex. 1009).

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