

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FLATWING PHARMACEUTICALS, LLC,
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2018-00169
Patent 9,566,289 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 1–15 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.

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. 9,566,290 (IPR2018-00170), 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. 9,566,289.” *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. x; Paper 4, 2.

B. The '289 Patent

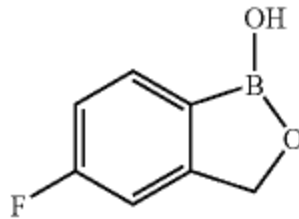
The '289 patent relates to boron-containing compounds useful for the topical treatment of onychomycosis and/or cutaneous fungal infections. Ex. 1001, Abstract. The invention is directed to compounds that are active against fungi and have physicochemical properties that facilitate penetration of the nail plate. *Id.* According to the Specification, current treatment for unguinal 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 the 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 penetrate the nail . . . [and] 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* followed by *T. mentagophytes*. *Id.* at 131:32–33.

The '289 patent claims a pharmaceutical formulation comprising 1,3-dihydro-5-fluoro-1-hydroxy-2, 1-benzoxaborole, which is also referred to as compound 1 (*see id.* at 137:52–61) and has the following chemical structure:



C. Illustrative Claim

Petitioner challenges claims 1–15 of the '289 patent. Claims 1, 4, and 12 are independent claims. Claim 1 is illustrative and is reproduced below:

1. A pharmaceutical composition comprising:
1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole, or a pharmaceutically acceptable salt thereof; and
a pharmaceutically acceptable topical carrier.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–15 of the '289 patent on the following grounds:

References	Basis	Claims challenged
Austin ¹ and Brehove ²	§ 103	1 and 2
Austin, Brehove, and Samour ³	§ 103	4–7, 10, and 11
Austin, Brehove, Samour, and the Excipients Handbook ⁴	§ 103	3, 8, 9, and 12–15
Austin and Freeman ⁵	§ 103	1 and 2
Austin, Freeman, and Samour	§ 103	4–7, 10, and 11
Austin, Freeman, Samour, and the Excipients Handbook	§ 103	3, 8, 9, and 12–15

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).

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 *Handbook of Pharmaceutical Excipients* (Arthur H. Kibbe, ed., 3d ed. 2000) (“Excipients Handbook,” Ex. 1011)

⁵ Freeman et al., WO 03/009689 A1, published Feb. 6, 2003 (“Freeman,” Ex. 1009).

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