UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS X LLC,
Petitioner,

v.

ANACOR PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-01776
Patent 7,582,621 B2

Before GRACE KARAFFA OBERMANN and MICHAEL P. TIERNEY, *Vice Chief Administrative Patent Judges*, and TINA E. HULSE, *Administrative Patent Judge*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Coalition for Affordable Drugs X LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 7,582,621 B2 (Ex. 1001, "the '621 patent"). Paper 1 ("Pet."). Anacor Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 17 ("Prelim. Resp.").

On February 23, 2016, we instituted an *inter partes* review of claims 1–12 of the '621 patent on two grounds of obviousness. Paper 24 ("Dec. Inst."), 15. Patent Owner filed a Response to the Petition. Paper 32 ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 47 ("Pet. Reply").

Patent Owner filed a motion to exclude certain exhibits. Paper 57. Petitioner filed an opposition (Paper 63) and Patent Owner filed a reply (Paper 65). Pursuant to authorization from the Board, Patent Owner also filed an Identification of New Arguments and Evidence in Petitioner's Reply (Paper 53) and Petitioner filed a response (Paper 60).[1]

Patent Owner filed observations on the cross-examinations of Petitioner's declarants, Stephen B. Kahl, Ph.D. (Paper 55) and S. Narasimha Murthy, Ph.D. (Paper 56). Petitioner filed responses to Patent Owner's observations. Paper 61 (Kahl); Paper 62 (Murthy).

[1] We do not find the arguments identified by Patent Owner to be impermissible new arguments and evidence in the Reply. Rather, we determine that the arguments were each in response to those set forth by Patent Owner in its Response, for the reasons stated by Petitioner. Paper 60, 1–3; 37 C.F.R. § 42.23(b) ("A reply may only respond to arguments raised in the corresponding opposition or patent owner response.").

An oral hearing was held on November 3, 2016, a transcript of which has been entered in the record. Paper 69 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). 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 that Petitioner has shown by a preponderance of the evidence that claims 1–12 of the '521 patent are unpatentable.

A. Related Proceedings

Petitioner has filed concurrently two other petitions for *inter partes* review of the claims of related U.S. Patent No. 7,767,657 B2 in IPR2015-01780 and IPR2015-01785. Pet. 5.

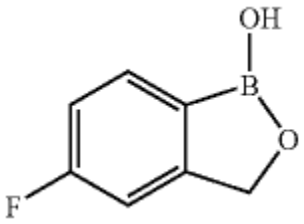
B. The '621 Patent

The '621 patent relates to boron-containing compounds useful for treating fungal infections, including infections of the nail and hoof known as ungual and/or periungual infections. Ex. 1001, Abstract, 1:12–13. One type of ungual and/or periungual fungal infection is onychomycosis. *Id.* at 1:15–17. 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 1:17–24.

Each of the approaches have major drawbacks. 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. *Id.* at 1:28–45. Surgical treatment is painful and undesirable cosmetically (or not realistic for animals such as horses). *Id.* at

1:46–52. And topical dosage forms cannot keep the drug in contact with the infected area for therapeutically effective periods of time. Moreover, because of the composition of the nail, topical therapy for fungal infections have generally been ineffective. *Id.* at 1:53–2:11. 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 2:36–39.

The '621 patent claims a method of treating an infection using 1,3-dihydro-5-fluoro-l-hydroxy-2, 1-benzoxaborole, which is referred to as either compound 1 (*see id.* at 32:10–17) or compound C10 (*see id.* at 51:55–61) in the Specification, and has the following chemical structure:



C. Illustrative Claim

Petitioner challenges claims 1–12 of the '621 patent. Claim 1 is illustrative and is reproduced below:

> 1. A method of treating an infection in an animal, said method comprising administering to the animal a therapeutically effective amount of 1,3-dihydro-5-fluoro-l-hydroxy-2, 1-benzoxaborole, or a pharmaceutically acceptable salt thereof, sufficient to treat said infection.

Claims 2–4 and 10 depend directly or indirectly from claim 1 and further recite specific infections that are treated with the claimed method. Claims 5 and 7 depend from claim 1 and further recite specific animals that are treated,

including humans. Claims 8 and 9 depend from claim 1 and further recite the site of administration of the drug. And claims 11 and 12 are independent claims that are similar to claim 1, but recite a method of treating onychomycosis in a human (claim 11) and a method of inhibiting growth of a fungus in a human (claim 12).

D. Grounds of Unpatentability Instituted for Trial

We instituted trial based on the following grounds of unpatentability:

References	**Basis**	**Claim(s) challenged**
Austin[2] and Brehove[3]	§ 103	1–12
Austin and Freeman[4]	§ 103	1–12

II. ANALYSIS

A. Person of Ordinary Skill in the Art

The level of ordinary skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) and *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art at the time the '621 patent was filed would have had an advanced degree (Master's or Ph.D.) or equivalent experience in chemistry, pharmacology, or biochemistry, and at least two years of experience with the research, development, or production of pharmaceuticals. Pet. 23 (citing Ex. 1006

[2] Austin et al., WO 95/33754, published Dec. 14, 1995 (Ex. 1002).
[3] Brehove, US 2002/0165121 A1, published Nov. 7, 2002 (Ex. 1003).
[4] Freeman et al., WO 03/009689 A1, published Feb. 6, 2003 (Ex. 1004).

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