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Paper No. 24
Entered: February 23, 2016

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

HULSE, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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.").

We have jurisdiction 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 Petition and Preliminary Response, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–12. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

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

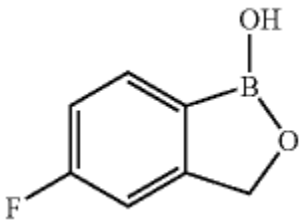
B. The '621 Patent

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 has 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 and, 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.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–12 of the '621 patent on the following grounds:

References	**Basis**	**Claim(s) challenged**
Austin[1] and Brehove[2]	§ 103	1–12
Austin and Freeman[3]	§ 103	1–12
Austin, Freeman, and Sun[4]	§ 103	9

Petitioner also relies on the Declarations of Stephen Kahl Ph.D. ("Kahl Decl.," Ex. 1006) and S. Narasimha Murthy Ph.D. ("Murthy Decl.," Ex. 1008).

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[1] Austin et al., WO 95/33754, published Dec. 14, 1995 (Ex. 1002).

[2] Brehove, US 2002/0165121 A1, published Nov. 7, 2002 (Ex. 1003).

[3] Freeman et al., WO 03/009689 A1, published Feb. 6, 2003 (Ex. 1004).

[4] Sun et al., US 6,042,845, issued Mar. 28, 2000 (Ex. 1005).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

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 ¶ 21; Ex. 1008 ¶ 34). Patent Owner largely agrees with Petitioner's definition, further adding that a skilled artisan must also have knowledge and experience with developing potential drugs candidates for treating onychomycosis and ungual and other infections. Prelim. Resp. 15–16.

We need not decide at this time whether one skilled in the art would have possessed the additional knowledge identified by Patent Owner for purposes of this Decision. Moreover, Patent Owner acknowledges that Petitioner's declarants purport to have experience in the additional fields (Prelim. Resp. 16), and the prior art itself is sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (holding the absence of specific findings on "level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015),

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