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 IPR2015-01780
Patent 7,767,657 B2

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

TIERNEY, *Vice Chief Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
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 1–24 of U.S. Patent 7,767,657 B2 (Ex. 1001, "the '657 patent"). Paper 3 ("Pet."). Patent Owner, Anacor Pharmaceuticals Inc. ("Patent Owner"), filed a Preliminary Response. Papers 7 and 17 ("Prelim. Resp."). We determined that there was a reasonable likelihood that Petitioner would prevail in challenging those claims as unpatentable. Pursuant to 35 U.S.C. § 314, we authorized an *inter partes* review to be instituted on February 23, 2016. Paper 24 ("Dec. on Inst.").

After institution, Patent Owner filed a Patent Owner Response. Paper 32 ("PO Resp."). Petitioner filed a Reply. Paper 47 ("Reply"). Patent Owner filed Motions for Observations Regarding the Cross-Examination Testimony of Stephen B. Kahl, Ph.D. (Paper 55) and S. Narasimha Murthy, Ph.D. (Paper 56), and Petitioner filed Responses (Papers 61 and 62, respectively). With Board authorization, Patent Owner filed an Identification of New Arguments and Evidence in Petitioner's Reply (Paper 53), and Petitioner filed a Response (Paper 60).[1] Patent Owner also filed a Motion to Exclude Evidence (Paper 57), Petitioner filed a Response (Paper 63), and Patent Owner filed a Reply (Paper 65).

[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; *see* 37 C.F.R. § 42.23(b) ("A reply may only respond to arguments raised in the corresponding . . . patent owner response.").

An oral hearing was held on November 3, 2016. A transcript of the hearing has been entered into the record of the proceedings as Paper 69 ("Tr.").

We have jurisdiction 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 that Petitioner has shown by a preponderance of the evidence that claims 1–24 are unpatentable.

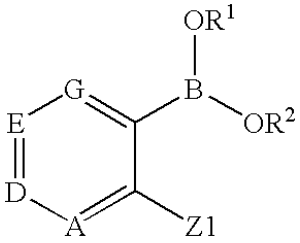
A. Related Proceeding

The claims of the '657 patent have been challenged in related *inter partes* review proceeding IPR2015-01785. Additionally, the '657 patent claims to be a continuation-in-part of U.S. Patent 7,582,621, which is involved in *inter partes* review IPR2015-01776. Pet. 4.

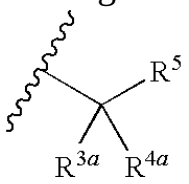
B. The '657 Patent

The '657 patent is titled "Boron-Containing Small Molecules." Ex. 1001. The '657 patent describes compounds useful for treating fungal infections, in particular, for topical treatment of onychomycosis and/or cutaneous fungal infections. *Id*. at Abstract. The compounds are said to have physiochemical properties that help facilitate the penetration of the nail plate. *Id*.

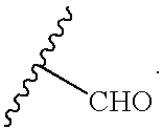
The '657 patent describes pharmaceutical formulations that include a pharmaceutically acceptable excipient and a compound of said invention. *Id*. at 139:35–37. According to the '657 patent "Summary of the Invention," said invention provides a structure that is described as having the following formula:



in which R1 and R2 are members independently selected from H, substituted or unsubstituted alkyl, substituted or unsubstituted heteroalkyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted heterocycloalkyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl. R1 and R2, together with the atoms to which they are attached, can be optionally joined to form a 4- to 7-membered ring. Z1 is a member selected from



and

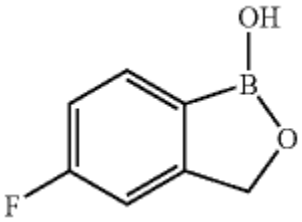


.

R3a and R4a are members independently selected from H, cyano, substituted or unsubstituted alkyl, substituted or unsubstituted heteroalkyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted heterocycloalkyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl. R5 is a member selected from halogen and OR8. R8 is a member selected from H, substituted or unsubstituted alkyl, substituted or unsubstituted heteroalkyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted heterocycloalkyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl. A is a member selected from CR9a and N. D is a member selected from CR10a and N. E is a member selected from CR11a and N. G is a member selected from CR12a and N. R9a, R10a, R11a and R12a are members independently selected from H, OR*, NR*R**, SR*, —S(O)R*, —S(O)2R*, —S(O)2NR*R**, nitro, halogen, cyano, substituted or unsubstituted alkyl, substituted or unsubstituted heteroalkyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted heterocycloalkyl,

substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl. Each R* and R** are members independently selected from H, substituted or unsubstituted alkyl, substituted or unsubstituted heteroalkyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted heterocycloalkyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl. R9a and R10a, along with the atoms to which they are attached, are optionally joined to form a ring. R10a and R11a, along with the atoms to which they are attached, are optionally joined to form a ring. R11a and R12a, along with the atoms to which they are attached, are optionally joined to form a ring. The combination of nitrogens (A+D+E+G) is an integer selected from 0 to 3.

Id. at 4:6–5:2. Example 4.2.j identifies the compound 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole as "C10," which has the following structure:



Id. at 180:20–27. The '657 patent provides several examples describing the antifungal activity of compound C10 and its ability to penetrate human nails. *Id*. at 189:15–196:46.

The '657 patent states that preferred compounds will have desirable pharmacological properties, including oral bioavailability, low toxicity, low serum binding, and desirable in vitro and in vivo half-lives. *Id*. at 165:66–166:2. According to the '657 patent, "[a]ssays may be used to predict these desirable pharmacological properties." *Id*. at 166:6–7. For example, "[t]oxicity to cultured hepatocyctes may be used to predict compound toxicity." *Id*. at 166:9–10.

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