Filed on behalf of Petitioner COALITION FOR AFFORDABLE DRUGS X LLC

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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 No.: 2015-01776
Patent No.: 7,582,621

DECLARATION OF STEPHEN KAHL PH.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF PATENT NO. 7,582,621

I, Stephen Kahl, Ph.D., hereby state the following:

I. INTRODUCTION

1. In this declaration, I am providing my expert opinions in support of Petitioner's Petition For *Inter Partes* Review of Patent No. 7,582,621 (the "'621 patent") and in reply to Patent Owner's Response Pursuant to 37 C.F.R. § 42.120.

2. I previously provided a declaration dated June 28, 2015, as part of the petition filed by Coalition for Affordable Drugs X LLC that led to this proceeding. My previous declaration is Ex. 1006. I also previously provided a declaration in reply to Patent Owner's Objections To Petitioner's Evidence Under 37 C.F.R. § 42.64(b)(1). This previous declaration is Ex. 1039.

3. I am competent to make this declaration based upon my personal knowledge and technical expertise.

4. All the exhibits I have considered and relied on in this proceeding are the kinds of documents I typically rely on when forming opinions, including the opinions I have offered in this proceeding.

5. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information that comes to light throughout this proceeding.

6. I have read the Declaration of Paul J. Reider, Ph.D. (Ex. 2034). His

declaration does not change my previous opinions.

7. I disagree with Dr. Reider's opinion that a person of ordinary skill in the art (POSITA) before February 16, 2005 would not have been aware of *Austin* because it "is an entirely different field than 'the research, development, or production of pharmaceuticals.'" (Ex. 2034 at ¶ 17.) I have often searched the patent and chemistry literature for information concerning compounds during my four decades of pharmaceutical research. My experience is that the patent and chemistry literature reports information relevant to pharmaceutical development (e.g., synthesis pathways, activity, and stability) in a variety of applications and settings. In my experience there is no reason to ignore *Austin*, and what it reports, simply because *Austin* does not discuss pharmaceutical development. *Austin's* disclosure is particularly useful for understanding the antifungal activity of the boron-containing compounds that it discloses and tests, like tavaborole.

8. One reason a POSITA searches the patent and chemistry literature when developing a new pharmaceutical product is to identify potential known compounds with relevant activity against a target disease. Here that includes compounds with antifungal activity. It is easier and less time consuming to start with a known compound that has known activity in most cases. This removes the trial and error associated with synthesizing and testing a large number of

compounds to identify a potential target compound. It does not appear that Dr. Reider addresses this significant reason for why a POSITA would find *Austin* relevant.

9. The ’621 patent inventors’ Journal of Medicinal Chemistry paper from 2006 (Ex. 2157) supports my opinion. In my experience, the medicinal chemistry community often reports findings in the Journal of Medicinal Chemistry after filing a patent application. The listed inventors of the ’621 patent appear to report their discovery of tavaborole for treatment of onychomycosis in their 2006 Journal of Medicinal Chemistry paper entitled “Discovery of a New Boron-Containing Antifungal Agent, 5-fluoro-1,3-dihydro-1-hyroxy-2,1-benzoxaborole (AN2690), for the Potential Treatment of Onychomycosis.” (*Id*.) The listed inventors relied on *Austin*, and its disclosure of certain synthesis pathways, to synthesize the 7-fluoro derivative through directed ortho metalation of 3-fluorobenzyl alcohol. (Ex. 2157 at 3 (right column).) This is a good example of medicinal chemists finding references that do not directly discuss pharmaceutical development relevant to the development of pharmaceutical products.

10. I also disagree with Dr. Reider’s opinion that tavaborole is not a preferred compound disclosed in *Austin*. As I testified during my deposition, when more than one molecule shares similar activity, I usually select the simplest

molecule, as would a POSITA. *Austin* discloses a preference for 5- and 6- fluoro or bromo 1,3-dihydro-1-hydroxy-2,1-benzoxaborole and O-esters thereof. (Ex. 1002 at Abstract.) Table 9 in *Austin* discloses antifungal and antibacterial data for benzoxaboroles, including the benzoxaboroles identified by name in the Abstract. Table 8 in *Austin* discloses antifungal and antibacterial data for O-esters of benzoxaboroles identified by name in the Abstract. The benzoxaboroles disclosed in Table 9 are simpler compounds (e.g., have lower molecular weights and are easier to synthesize) than their corresponding O-ester derivatives disclosed in Table 8.

11. Significantly, of the compounds that had the most potent activity in the Abstract, Table 8 and Table 9, tavaborole (Example 64 in Table 9) is the simplest and lowest molecular weight compound with the best activity. This makes tavaborole the first choice for future development, particularly given the consideration that a POSITA was developing a topical formulation for nail penetration. Dr. Reider's opinions regarding which compounds he believes are preferred compounds in *Austin* do not consider that the compound will be used for topical treatment of onychomycosis. In addition, Dr. Reider does not provide a reason why a POSITA would choose a larger, more complicated O-ester derivative when there are simpler, lower molecular weight preferred compounds with the

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