Served 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 IPR2015-01776 (Patent 7,582,621 B2)

PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION TESTIMONY OF S. NARASIMHA MURTHY, PH.D.

I. INTRODUCTION

Pursuant to the Scheduling Order (Paper No. 25), Petitioner hereby submits its Response to Patent Owner's Motion for Observations Regarding the Cross-Examination Testimony of S. Narasimha Murthy, Ph.D. (Paper No. 56.) In accordance with the Scheduling Order, Petitioner's response to each of Patent Owner's observations is equally concise and specific.

II. RESPONSE TO OBSERVATIONS

1. Petitioner agrees with Dr. Murthy's testimony that *Austin* alone furnishes a reasonable expectation of success in treating onychomycosis in view of the knowledge of a person of ordinary skill in the art as well as the limited disclosure of the provisional application (Ex. 1064) to which U.S. Patent No. 7,582,621 claims priority. (*See* Ex. 2207 at 656:12-657:24.) However, Dr. Murthy further testified that "the claims were obvious, not only in *Austin*, it was also when combined with *Brehove* and *Freeman* and other references." (*Id.* at 758:22-759:3.) This testimony is relevant because Petitioner never argued that claims 1-12 of U.S. Patent No. 7,582,621 ("the '621 Patent") are unpatentable under 35 U.S.C. § 102 over *Austin* alone. (*See* Paper No. 1 at 8; Paper No. 24 at 4, 15-16); rather, that the claims are unpatentable based on a 35 U.S.C. § 103 combination of references (Paper No. 1 at 8; Paper No. 47 at 1, 28).

2. Dr. Murthy testified that "[t]he information that's . . . provided in *Austin* is all [that] a POSITA would need . . . **to take the molecule further and develop a potential medication for the treatment of onychomycosis**." (Ex. 2207 at 657:21-24, emphasis added.) While Dr. Murthy testified that *Austin* alone provides a reasonable expectation of success for each limitation of claims 1, 4 and 6 of the '621 Patent (*see id.* at 658:20-661:22), Dr. Murthy further testified that "the claims were obvious, not only in *Austin*, it was also when combined with *Brehove* and *Freeman* and other references" (*id.* at 758:22-759:3). This testimony is relevant because Petitioner never argued that claims 1, 4 and 6 of the '621 Patent were unpatentable under 35 U.S.C. § 102 over *Austin* alone (*see* Paper No. 1 at 8; Paper No. 24 at 4, 15-16); rather, that the claims are unpatentable based on a 35 U.S.C. § 103 combination of references (Paper No. 1 at 8; Paper No. 47 at 1, 28).

3. In contrast to Patent Owner's allegation that *Austin* is not relevant or analogous art, Dr. Murthy testified that "treating industrial fungus and nail fungus is almost the same field. It's . . . overlapping fields." (Ex. 2207 at 717:9-11.) When asked to elaborate, Dr. Murthy stated: "Well . . . in *Austin*, he discloses how the boron-containing compounds can be used for treating fungus. So the fungus that he discloses is one of the human pathogens, and that human pathogen is . . . one of the organisms causing onychomycosis. So there's a lot of relevance between *Austin* and '621 patent." (*Id.* at 717:13-19.) Dr. Murthy further testified that "*Austin* and

the patent owner of '621 are both trying to develop fungicides, and those fungal organisms are the most common human pathogens. So the considerations would not be very different between these two inventions." (*Id.* at 724:7-11.) This testimony is relevant because it rebuts Patent Owner's allegation that *Austin* is not relevant or analogous art. (*See* Paper No. 32 at 27-33.) Petitioner agrees with Dr. Murthy that *Austin* is relevant prior art, or at a minimum analogous prior art, to the '621 Patent. (*See* Paper No. 47 at 2, 11-12.)

4. Dr. Murthy stated that he was not an expert in mycology. (*See* Ex. 2207 at 651:23-24.) Despite Patent Owner's assertion, this testimony is irrelevant because Dr. Murthy's obviousness analysis does not require expertise in mycology (*see* Paper No. 1 at 23), nor does Patent Owner's proposed definition of a person of ordinary skill in the art require expertise in mycology (*see* Paper No. 17 at 16; Paper No. 32 at 21-22). Rather, when questioned about paragraph 90 of his declaration (which discusses various antifungal drugs that exhibit better effectiveness against dermatophytes than against *C. albicans*), Dr. Murthy replied that this is "general information [in] my background knowledge, so it doesn't require a mycologist to understand." (Ex. 1044 ¶ 90; Ex. 2207 at 649:18-650:2.) With respect to understanding and evaluating MIC data, Dr. Murthy stated that this was also part of his background knowledge. (*See* Ex. 2207 at 684:21-24.) This

testimony is relevant because it supports Dr. Murthy's qualifications to conduct an obviousness analysis of the claims of the '621 Patent.

5. Petitioner does not agree with Patent Owner's characterization of the record. Dr. Murthy previously opined that tavaborole, within the context of boron-containing antifungals and in view of shared antifungal activity against *Candida* species, would be expected to share other activities with the boron compounds of *Brehove* and *Freeman*, "such as the **inhibition of additional fungi responsible for onychomycosis**." (Ex. 1008 ¶¶ 100-01, 133.) Although Dr. Murthy confirmed during his first deposition that most antifungals exhibit broad spectrum activity against different fungi, including dermatophytes and *Candida* species (*see* Ex. 2032 at 531:8-535:21), the Patent Owner argued that antifungal activity against *C. albicans* was **not predictive** of activity against dermatophytes, citing a reference concerning non- boron-based antifungals (*see* Paper 32 at 11, 44-46; Ex. 2035 ¶¶ 63-64, 114, 123, 132). During his second deposition, Dr. Murthy's testified that, "because **most** of . . . the antifungal drugs that are effective against *C. albicans* are also effective against dermatophytes . . . the POSA would be motivated to select tavaborole as a potential therapeutic model for treating onychomycosis." (Ex. 2207 at 711:2-8, emphasis added; *see also id.* at 697:11-698:3, 699:12-25, 702:15-21.) This testimony is relevant because it rebuts Patent Owner's arguments that

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