IN THE 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. IPR2015-01776 Patent No. 7,582,621

PATENT OWNER'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION TESTIMONY OF S. NARASIMHA MURTHY, Ph.D.

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IPR2015-01776

I. Introduction

In accordance with: (i) The Trial Practice Guide, Federal Register Vol. 77, No. 157, 48756 at 48767–68 and (ii) the Scheduling Order (Paper No. 25) as modified by the Joint Notice of Stipulation to Adjust Schedule (Paper No. 28) and the Second Joint Notice of Stipulation to Adjust Schedule (Paper No. 31), Patent Owner hereby submits the instant Motion for Observations Regarding the Cross-Examination Testimony of S. Narasimha Murthy, Ph.D. taken on September 17, 2016. The transcript of this testimony has been filed as Exhibit 2207.

Patent Owner requests that the Board enter the instant Motion and consider the observations. Observations 1–14 below pertain to the deposition testimony of S. Narasimha Murthy, Ph.D., obtained on September 17, 2016, after Patent Owner filed its last substantive paper. In addition, and in accordance with the Trial Guide, each of observations 1–14 below provides in a single paragraph a concise statement of the relevance of the precisely identified testimony to a precisely identified argument.

II. Observations

1. In Ex. 2207 at 656:12-657:24, Dr. Murthy affirmed that the Austin reference alone provides a reasonable expectation of success to treat onychomycosis and stated, "[t]he information that's -- that's provided in Austin is all what [*sic*] a POSITA would need to -- to take the molecule further and develop

a potential medication for the treatment of onychomycosis." At 711:11-14, Dr. Murthy testified that "my position is that the POSA could just look at the Austin and have a reasonable expectation of success using tavaborole to treat onychomycosis." This testimony is relevant because this argument was not in the Petition and constitutes a new alleged ground of invalidity presented for the first time with Petitioner's Reply To Patent Owner's Response ("Reply," Paper No. 47).

2. In Ex. 2207 at 658:20-665:15, Dr. Murthy testified that Austin alone discloses every individual limitation of Claims 1, 4 & 6 of the '621 Patent. This testimony is relevant because this argument was not in the Petition and constitutes a new alleged ground of invalidity presented for the first time with Petitioner's Reply.

3. In Ex. 2207 at 716:16-717:1, Dr. Murthy testified that the '621 Patent discloses tavaborole "for treating onychomycosis," but Austin discloses the compound "for some other purpose," *i.e.*, "industrial biocides." At 723:11-19, Dr. Murthy testified that "the protection of plastics from -- from fungal -- fungal growth" was the problem that the inventors of Austin were trying to solve. This testimony is relevant because of Dr. Murthy's prior assertion that Austin is analogous art to the '621 Patent. *See* Ex. 1044 ¶¶ 42-43; Reply pp. 2 & 11-12.

4. In Ex. 2207 at 651:23-24, Dr. Murthy testified, "I'm not an expert in mycology." This testimony is relevant because Dr. Murthy's obviousness analysis

relies on mycological arguments. See, e.g., Ex. 1044 ¶ 88 (arguing that "antifungals that show efficacy against C. albicans are likely to show efficacy against dermatophytes").

5. In Ex. 2207 at 699:21-25, Dr. Murthy testified that "in most cases, if you are sure that it [*i.e.*, a compound] is active against *C. albicans* and if you know the MIC value, that's predictable of antifungal activity against dermatophytes." At 710:16-711:14, Dr. Murthy testified that a POSA would have a reasonable expectation of success based on Austin alone in part because "antifungal drugs that are effective against C. albicans are also effective against dermatophytes." At 697:8-698:3, Dr. Murthy testified that he was aware of this alleged relationship between yeast and dermatophyte activity before his first declaration, but did not make an argument based on the relationship until his second declaration. This testimony is relevant because this argument was not in the Petition and was presented for the first time with Petitioner's Reply. This testimony is also relevant because Dr. Murthy previously testified that a POSA would have a reasonable expectation that tavaborole would have activity against dermatophytes because structurally similar compounds allegedly possessed activity against dermatophytes. See Ex. 1008 ¶¶ 100-01 (extrapolating the activity of Brehove's compounds to tavaborole); id. at ¶¶ 132-33 (extrapolating the activity of Freeman's compounds to tavaborole).

6. In Ex. 2207 at 667:21-668:11, Dr. Murthy affirmed that a POSA would only need to know a compound's MIC value and molecular weight in order to determine whether the compound would have sufficient nail penetration to successfully treat onychomycosis. This testimony is relevant because this argument and the evidence Petitioner used to support it (*e.g.*, Mertin & Lippold, Ex. 1065; Kobayashi, Ex. 1076) were not in the Petition, and were presented for the first time with Petitioner's Reply. This testimony is also relevant because Dr. Murthy previously asserted that a POSA would predict tavaborole's nail penetration based on the known nail penetration of structurally similar compounds. *See* Ex. 1008 ¶¶ 95 & 102 (predicting nail penetration for tavaborole based on a comparison with Freeman's compounds); *id.* at ¶ 134 (predicting nail penetration for tavaborole based on a comparison with Freeman's compounds).

7. In Ex. 2207 at 670:1-7, Dr. Murthy testified that he knew about the Mertin & Lippold reference (Ex. 1065) before his first declaration and "ever since I started working on the nail penetration." At 746:14-747:1, Dr. Murthy testified that he knew about Kobayashi (Ex. 1076) for years before this proceeding began. This testimony is relevant because these references are central to Petitioner's new argument that molecular weight predicts nail penetration, *see* Reply p. 18; Ex. 1044 ¶¶ 64 & 69–70; Ex. 2207 at 669:14-17, but they were not in the Petition and were presented for the first time with Petitioner's Reply.

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