

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 STEPHEN B. KAHL, 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 Stephen B. Kahl, Ph.D. (Paper No. 55.) 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. Kahl's testimony in Ex. 2206 at 66:1-6 that *Austin* alone furnishes a reasonable expectation of success 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. However, Petitioner does not and has not argued that claims 1-12 of U.S. Patent No. 7,582,621 are unpatentable under 35 U.S.C. § 102 over *Austin* alone. (See Paper No. 1 at 8; see Paper No. 24 at 4, 15-16.) It is clear from the Petition and reply brief that Petitioner's grounds for unpatentability are based on a 35 U.S.C. § 103 combination of references. (Paper No. 1 at 8; Paper No. 47 at 1.)

2. In Ex. 2206 at 67:1-25 and 70:19-71:12, Dr. Kahl testified that he reviewed and relied on Ex. 1028, titled "Drug delivery to the nail following topical application," while preparing his declaration in support of Petitioner's reply and that earlier in his deposition he did not recall that he looked at Ex. 1028 because it

was among the “large number of materials” he had to review. In Ex. 2206 at 61:14-17 and 62:14-17, Dr. Kahl testified that Ex. 1028, which discloses drug delivery to the nail, “is rather outside my area of expertise.” In rebuttal to Patent Owner’s expert Dr. Reider, Dr. Kahl’s declaration addresses the well-accepted more general principle that “topical formulations for delivery of a compound significantly reduce concerns related to systemic toxicity.” (Ex. 1043 at ¶ 23; Ex. 2033 (Dr. Kahl’s First Deposition Testimony) at 406:7-408:20 (“the plasma concentrations of topically administered agents are typically orders of magnitude less than what they would be if that drug were administered orally”); *see also* Paper No. 32 at 62 (“[a]s one professor stated, ‘[t]opical therapy avoids the problems associated with the adverse events and drug interactions of systemic drugs and may have greater patient compliance.’”); Ex. 2041 at 24.)

IPR2015-01776
Patents 7,582,621

Respectfully submitted,

MERCHANT & GOULD, P.C.

Respectfully submitted,

Date: October 11, 2016



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CERTIFICATE OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on October 11, 2016, a complete and entire copy of PETITIONER'S RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION TESTIMONY OF STEPHEN B. KAHL, PH.D. was served by email, by agreement of the parties to:

areister@cov.com; and
elongton@cov.com.

Respectfully submitted,

MERCHANT & GOULD P.C.

By: 

Counsel for Petitioner