By: Jeffrey D. Blake, Esq.
Matthew L. Fedowitz, Esq.
MERCHANT & GOULD P.C.
191 Peachtree Street N.E., Suite 3800
Atlanta, GA 30303
jblake@merchantgould.com
mfedowitz@merchantgould.com
Main Telephone: (404) 954-5100
Main Facsimile: (404) 954-5099

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC
Petitioner

v.

NPS PHARMACEUTICALS, INC.
Patent Owner

Case No. IPR2015-01093
Patent No. 7,056,886

PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE REPLY DECLARATION OF ANTHONY PALMIERI III (EX. 1041)

TABLE OF CONTENTS

I. INTRODUCTION

Petitioner Coalition for Affordable Drugs II LLC filed its Reply to Patent Owner's Response, supported by the reply declaration of its expert Dr. Anthony Palmieri III, on April 20, 2016. (Paper 40 and Ex. 1041.) Patent Owner is now worried by the substance of Dr. Palmieri's reply declaration. Patent Owner's solution to this problem is to submit unauthorized sur-reply arguments to the points raised by Dr. Palmieri under the guise of a motion to exclude. This is plainly improper. The Board should not credit these thinly-veiled sur-reply arguments (which lack any merit as bases to exclude), and the Motion should be denied.

The first argument in Patent Owner's Motion – that Dr. Palmieri is not a qualified expert – is plainly contradicted by the record. Patent Owner initially questions Dr. Palmieri's background. Dr. Palmieri's qualifications speak for themselves, including his academic degrees in Pharmaceutics and Pharmacy, faculty positions, work in the pharmaceutical industry and service on numerous editorial boards of pharmaceutical publications – all of which are acknowledged by Patent Owner. Through his experience, Dr. Palmieri is well-versed in ways to stabilize formulations of pharmaceutical compounds, including those involving peptides, which is the subject matter of the claims of the '886 patent.

Patent Owner then turns to "other evidence that Dr. Palmieri is not a qualified expert," and lists a number of factors, such as optimum pH and "quality

control" or batch processing in drug manufacturing, that purportedly should have been considered in analyzing the obviousness of the claims of the '886 patent. Patent Owner does not believe this "other evidence" actually proves Dr. Palmieri is not qualified; indeed, Patent Owner's filing of Observations on Dr. Palmieri's testimony is a *de facto* concession that he is qualified. In reality, this "other evidence" is just an effort to make sur-reply arguments to the substance of Dr. Palmieri's reply declaration, and it should be ignored.

The second argument in Patent Owner's Motion – that Paragraphs 10-19 of the Palmieri declaration should be excluded – is both untimely and wrong. Patent Owner's objections to Paragraphs 10-19 are raised ***for the first time*** in this Motion. This violates the requirement of 37 C.F.R. 42.64(b)(1) that the objection must have been filed within five business days of the service of the Palmieri declaration.

Moreover, Paragraphs 10-19 are relevant because they explain that alleged "complexities" in creating the formulations claimed in the '886 patent that were identified by Patent Owner's expert Dr. Carpenter were not discussed anywhere in the '886 patent. Dr. Palmieri is simply pointing out an inconsistency – Dr. Carpenter argues (with no real support) that these complexities are important but the patent doesn't mention them. This is relevant information that the Board can give the weight it thinks is appropriate. Patent Owner responds to this information

by insinuating the inventor may have taken these complexities into account even if they are not identified in the '886 patent, which is improper sur-reply testimony.

Finally, these paragraphs are not hearsay because they do not contain out of court statements by the inventor, only a discussion of what is and is not discussed in the '886 patent.

Dr. Palmieri is a qualified expert, and the substance in his reply declaration is relevant and non-hearsay. This Motion should be denied.

II. LEGAL STANDARD

The Federal Rules of Evidence apply in an IPR proceeding. 37 C.F.R. § 42.62. Fed. R. Evid. 702 requires that an expert witness must be "qualified as an expert by knowledge, skill, experience, or education," and the testimony must "help the trier of fact to understand the evidence or to determine a fact in issue." The expert's testimony must also be "based on sufficient facts or data" and be "the product of reliable principles and methods" and the expert must "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702.

"So long as the expert's testimony rests upon 'good grounds,' it should be tested by the adversary process—competing expert testimony and cross-examination…." *In re TMI Litig*., 193 F.3d 613, 692 (3rd Cir. 1999) (quoting *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)). If the objections to evidence go to the weight of the expert's testimony

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