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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 RESPONSE TO MOTION PRESENTING PATENT OWNER'S OBSERVATIONS REGARDING CROSS-EXAMINATION OF ANTHONY PALMIERI, Ph.D.

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I. INTRODUCTION

The Coalition for Affordable Drugs II LLC ("Petitioner") submits this Response to the Motion Presenting Patent Owner's Observations Regarding Cross-Examination of Anthony Palmieri, Ph.D. (Paper 47, "Observations"). These responses to observations are timely submitted pursuant to a joint stipulation between the parties resetting the due date for these responses to May 31, 2016.

On May 27, 2016, a teleconference between the Board and the parties was held to provide guidance on how Petitioner should respond to Patent Owner's improper Observations. During the teleconference, the Board authorized Petitioner to include an introduction in its Response to Patent Owner's Observations explaining Petitioner's objections and stating the relevant authority for those objections.

A. Patent Owner's Observations are an Unauthorized Sur-Reply

The Trial Practice Guide, 77 Fed. Reg. 157, 48756-73 (August 14, 2012) clearly explains the purpose of observations on cross-examination is to draw the Board's attention to relevant cross-examination testimony that "occurs after a party has filed its last substantive paper on an issue." *Chums, Inc. v. Cablz, Inc*. IPR2014-01240, Paper 32, page 2. The Trial Practice Guide, 77 Fed. Reg. 157, 48756-73 (August 14, 2012) sets forth requirements for observations on cross-examination.

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> An observation should be a concise statement of the relevance of identified testimony to an identified argument or portion of an exhibit (including another part of the same testimony)…An observation…is not an opportunity to raise new issues, re-argue issues, or pursue objections. Each observation should be in the following form:
>
> In exhibit __, on page __, lines __, the witness testified __. This testimony is relevant to the __ on page __ of __. The testimony is relevant because __.

Rather than following the Trial Practice Guide, Patent Owner instead filed Observations that are in the improper format, excessively long, argumentative, and attempt to introduce new exhibits into the record. These Observations amount to an unauthorized sur-reply filed under the veil of Observations. If Patent Owner wished to respond to arguments in the Petitioner's reply, the proper mechanism was to contact the Board and request permission for a sur-reply. Patent Owner chose not to do so, and it should not be allowed to submit a sur-reply through improper observations. *See Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 37.

B. Requirements for Filing Observations

Each of the Observations provided for Dr. Palmieri do not follow the format required by the Trial Practice Guide as set forth above. *See* Observations 1-33.

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Instead, Patent Owner's Observations attempt to masquerade as being in the proper format by using phrases and terms such as "the witness testified" and "relevant." However, a cursory review of Dr. Palmieri's Observations reveal that they do not follow the Board's required format. *Id*.

The same is true regarding the argumentative nature of Patent Owner's Observations, which resemble a brief and are an attempt to introduce new evidence, re-argue issues and raise new issues. *See* Observation 3 arguing that Dr. Palmieri "misstated that Dr. Carpenter agreed that a formulator would not need to know formulation basics and would consult others for basics"; Observations 24 and 25 arguing that the identified testimony "evidences [Dr. Palmieri's] lack of expertise and his use of hindsight"; and Observation 32 raising the new issue that "Petitioner attempts to raise enablement issues in these IPRs."

This is improper as the Board is clear in its requirements that observations must be a concise statement of the relevance of precisely identified testimony to a precisely identified argument or portion of an exhibit. *Medtronic, Inc. v. NuVasive, Inc*., IPR2013-00506, Paper 37, p. 2. In addition, the entire observation should not exceed one short paragraph. *Id.* Patent Owner's Observations disregard this requirement. *See* Observations 1, 2, 5, 8, 9, 10, 12, 14, 15, 18, 20, 22, and 27.

Further, each observation should cite to one portion of testimony and not several pages and this is a basis upon which observations may be

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dismissed. *Medtronic, Inc. v. NuVasive, Inc*., IPR2013-00506, Paper 37, pp 3-4. Patent Owner also did not follow this requirement. For example, Observation 1 provides seventeen citations to Ex. 2171 (333:12-334:19; 487:22-498:1; 337:21-338:11; 629:15-630:20; 453:18-454:8; 426:13-18; 570:15-25; 602:25-603:4; 603:24-604:6; 622:12-624:5; 624:16-22; 632:22-633:4; 605:12-606:2; 606:13-607:5; 611:19-613:13; 617:15-618:5; and 692:3-696:7). In fact, many citations are to extended portions of deposition transcript spanning multiple pages, such as 333:12-334:19, 487:22-498:1, 622:12-624:5, 611:19-613:13, and 692:3-696:7 for Observation 1 alone. *See also* Observations 2-9, 12-18, 25, and 33 as additional examples of improperly providing citations to multiple portions of testimony in a similar manner as Observation 1.

The Board may refuse entry of excessively long or argumentative observations. Trial Practice Guide at p. 48768; and, *Medtronic, Inc. v. NuVasive, Inc*., IPR2013-00506, Paper 37, p. 2. Indeed, the majority of Patent Owner's Observations are lengthy. *See* Observations 1, 2, 5, 8, 9, 10, 12, 14, 15, 18, 20, 22, and 27. The Board has precedent for dismissing excessively long observations. *Medtronic, Inc. v. NuVasive, Inc*., IPR2013-00506, Paper 37, page 3.

Finally, the Board has held that no new exhibits are permitted with Observations by stating that *only* testimony from cross-examination should be present in Observations. *Medtronic, Inc. v. NuVasive, Inc.,* IPR2013-00506, Paper

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