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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. IPR2015-001093
Patent No. 7,056,886

**PETITIONER'S RESPONSE TO MOTION PRESENTING
PATENT OWNER'S OBSERVATIONS REGARDING
CROSS-EXAMINATION OF IVAN HOFMANN**

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 Ivan Hofmann (Paper 48 in IPR2015-01093, “Hofmann 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 Hofmann Observations. During the teleconference, the Board authorized Petitioner to include an introduction in its Responses to Patent Owner’s Observations explaining Petitioner’s objections and stating the relevant authority for those objections.

1. 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 sets forth requirements for observations on cross-examination:

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.

Rather than following the Trial Practice Guide, Patent Owner instead filed Observations that are argumentative and attempt to introduce new exhibits into the record. Petitioner objects to this improper use of the observations, which amount to an unauthorized sur-reply. If Patent Owner wished to respond to arguments in 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 substitute a sur-reply through improper observations. *See Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 37.

2. Requirements for Filing Observations

It is clear that many of Patent Owner's Observations, which resemble a brief, re-argue issues and raise new issues. *See, e.g.*, Observations 3 and 4, which raise new issues about the scope of the blocking '379 patent and how that blocking patent affects the long-felt need and commercial success analysis. Additional examples of new or re-argued issues are addressed below in response to the specific Observations. This is improper, as it does not follow the Board's

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, many of the Hofmann Observations violate the requirement that the entire observation should not exceed one short paragraph. *Id.* Further, each observation should cite to one portion of testimony and not to large numbers of pages in one citation. *Medtronic, Inc. v. NuVasive, Inc.*, IPR2013-00506, Paper 37, pp 3-4. For example, Petitioner objects that the Hofmann Observations inappropriately cite to the following extended portions of Mr. Hofmann's testimony: citations to pp. 62:12-83:19 (Observation 3), pp. 159:9-169:14 (Observation 7), pp. 120:9-128:22 (Observation 14), pp. 192:15-200:19 (Observation 17) and pp. 257:20-267:13 (Observation 21).

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 37, page 4, footnote 2. Again, Patent Owner did not follow this requirement. For example, Patent Owner attempts to improperly use the Hofmann Observations to introduce new Exhibit Nos. 2161-2169 and 2172 in IPR2015-00990 and new Exhibit Nos. 2162-2169 and 2172-2173 in IPR2015-01093. Patent Owner's intention to include new exhibits is obvious given that it cites directly to new

exhibits in the Hofmann Observations (see citations to Exs. 2161-2162 in the -990 matter in Observation 9, Exs. 2162 and 2173 in the -1093 matter in Observation 9, Ex. 2164 in both matters in Observation 15, and Ex. 2168 in both matters in Observation 19) and cites to Hofmann deposition testimony about those exhibits.

Patent Owner argued during the teleconference with the Board on May 27, 2016, that Petitioner waived the right to object to these new exhibits. That is not correct. Petitioner objected to the use of these exhibits during the Hofmann deposition. After the deposition, Petitioner had no way to know they would be used improperly as part of the Hofmann Observations. Once Petitioner saw that the new exhibits were used in the Hofmann Observations, Petitioner promptly objected to the Board that the Hofmann Observations were improper and should be expunged

Given that Patent Owner's Observations are argumentative, fail to follow the proper requirements set forth in the Trial Practice Guide, are excessively long, and attempt to introduce new exhibits into the record, these Observations amount to an unauthorized sur-reply. Accordingly, Petitioner objects to them.

II. RESPONSES TO OBSERVATIONS

1. *Response to Observation 1* – In Ex. 2170, at 10:4-23 and 11:20-12:17, Mr. Hofmann testified as to his qualifications as an expert in this matter and the requirements for becoming a member of LES. This testimony is relevant to

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