IN THE 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.

Cases IPR2015-00990 and IPR2015-01093
(Patent 7,056,886 B2)[1]

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

[1] Pursuant to the Board's Scheduling Order in these IPRs, "the word-for-word identical paper is filed in each proceeding identified in the heading." *See, e.g.*, IPR2015-00990, Paper 29, footnote 1.

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Pursuant to 37 C.F.R. 42.64(c), the Trial Practice Guide, 77 Fed. Reg. 157, 48756-73, 48767 (August 14, 2012) and the Scheduling Orders in these IPRs, Patent Owner NPS Pharmaceuticals Inc. ("NPS") submits this motion exclude the Reply Declaration of Anthony Palmieri III, Ex. 1041.

I. INTRODUCTION

The opinions in the Reply Declaration (Ex. 1041) are inadmissible under Fed. R. Evid. 702. Dr. Palmieri has shown in his depositions that he is not qualified to offer expert testimony in protein/peptide formulation science, which is the field of the '886 patent. The opinions expressed in Ex. 1041 should be excluded because they are not based on sufficient facts or data, they are not the product of reliable principles and methods, and they are not reliably applied to the facts of this case.

Certain testimony is also inadmissible hearsay and irrelevant speculation under Fed. R. Evid. 801 and 401. In Ex. 1041, ¶¶ 10-19, Dr. Palmieri purports to know what was in the mind of the '886 inventor, as grounds for disregarding the challenges the inventor faced. Dr. Palmieri of course has no personal knowledge of the inventor's work and no access to her thoughts. His opinions arising from surmise about the inventor should be excluded. Such testimony is also irrelevant under Rule 401, because the inventor is not a person of ordinary skill in the art, nor is a patent required to identify any or all of the problems the invention overcame.

II. LEGAL STANDARD FOR MOTION TO EXCLUDE

"A party wishing to challenge the admissibility of evidence must object timely to the evidence at the point it is offered and then preserve the objection by filing a motion to exclude the evidence." Trial Practice Guide, 77 Fed. Reg. 48765, 48767 (Aug. 14, 2012) (citing 37 C.F.R. § 42.64). "A motion to exclude evidence must: (a) Identify where in the record the objection originally was made; (b) Identify where in the record the evidence sought to be excluded was relied upon by an opponent; (c) Address objections to exhibits in numerical order; and (d) Explain each objection. *Id*.

Expert testimony in an IPR is generally governed by the Federal Rules of Evidence. 77 Fed. Reg. 157, at 48758. Fed. R. Evid. 702 ("Rule 702") provides that a witness must be "qualified as an expert by knowledge, skill, experience, training, or education." The testimony must be: (a) helpful specialized knowledge; (b) "based on sufficient facts or data;" and (c) "the product of reliable principles and methods;" which in turn are (d) "reliably applied … to the facts of the case."

Rule 702 is consistent with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-95 (1993), which provides for unreliable testimony to be excluded. Pertinent factors under *Daubert* include whether the expert's theory is subjective and conclusory, has been subject to peer review and publication, and has been generally accepted in the scientific community. Another factor is whether the

expert has developed opinions "expressly for purposes of testifying." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). An opinion cannot extrapolate to an unfounded conclusion, *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), and cannot ignore other obvious explanations, *Claar v. Burlington N.R.R.*, 29 F.3d 499, 502-03 (9th Cir. 1994). The expert must testify from a relevant and reliable discipline, *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1175 (1999), and must use "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997).

Hearsay evidence is inadmissible under Rule 801, when a statement, other than one made by the declarant, is offered in evidence "to prove the truth of the matter asserted." *Air Land Forwarders, Inc. v. US*, 172 F. 3d 1338, 1342 (Fed. Cir. 1999). A "statement" under Rule 801 is defined as "a person's oral assertion, written assertion, or nonverbal conduct, if the person intended it as an assertion."

"Irrelevant evidence is not admissible" under Rule 401 and 402, when the evidence does not tend "to make a fact more or less probable than it would be without the evidence" or the fact is not of "consequence in determining the action." Fed. R. Evid. 401 and 402; *see also Daubert*, 509 U.S. at 587 (1993); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997).

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