

For the Petitioner:

Paper No. _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
HAYMAN ORANGE FUND SPC – PORTFOLIO A;
HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT FUND, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS, and ERICH SPANGEBERG,
Petitioners,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

PETITIONER'S OBJECTIONS TO EVIDENCE

Pursuant to 37 C.F.R. § 42.64(b), Petitioner objects under the Federal Rules of Evidence (“FRE”) and 37 C.F.R. § 42.62 to the following exhibits cited in Patent Owner’s Preliminary Response (“POPR”), dated January 6, 2016. Petitioner’s Objections to Evidence are timely filed under 37 C.F.R. § 42.64.(b)(1).

Petitioner serves Patent Owner (“PO”) with these objections to provide notice that Petitioner may move to exclude the challenged exhibits under 37 C.F.R. § 42.64(c) unless Patent Owner cures the defects associated with the challenged exhibits defined herein.

Exhibit	PO Description	Page(s) of POPR citing	Objection(s)
Contained within 1007 at pages 14-35.	Declaration under 37 CFR 1.132 of Dr. Katherine Dawson filed in U.S. Patent Application No. 13/372,426	31-38	<p>To the extent the Dawson declaration is relied upon for secondary considerations of non-obviousness, there is no nexus to the claimed methods. The unexpected results evidence presented in an <i>ex parte</i> examination is not binding in a subsequent <i>inter partes</i> cases involving the same application.</p> <p>FRE 401 (Relevance “has any tendency to make a fact more or less probable than it would be without the evidence” and “is of consequence in determining the action”).</p>

			<p>FRE 402 (Irrelevant evidence is not admissible) FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)</p>
2005	<p>Ludwig Kappos et al., “A Randomized, Placebo-Controlled Phase 2 Trial of a Novel Oral Fumarate, BG00012, in Patients With Relapsing-Remitting Multiple Sclerosis,” from the 15th meeting of the European Neurological Society, Vienna Austria (June 18-22, 2005) (presented on June 20, 2005)</p>	24	<p>This exhibit is confusing, lacks authentication, and constitutes and/or contains hearsay. Specifically, a first petition based, in part, on a Kappos 2005 reference was denied. This IPR trial was instituted, in part, based on a Kappos 2006 reference. As stated in the POPR (<i>see e.g.</i>, POPR at 7), Kappos 2006 provides the results of a Phase II study. Exhibit 2005 is purportedly dated June 18-22, 2005, contains no results, and, at a minimum, confuses which Kappos reference is being referred to. In addition, Exhibit 2005 lacks authentication and, thus, constitutes and/or contains hearsay. To the extent PO might rely on Exhibit 2013 for authentication, that exhibit refers to “P 574,” an identification not found on Exhibit 2005.</p> <p>FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)</p>

			<p>FRE 901 (lacking authentication) FRE 902 (evidence is not self-authenticating) FRE 802 (not an exception to the rule against hearsay)</p>
2006	<p>Final Program for the Fifteenth Meeting of the European Neurological Society, June 18-22, 2005, Vienna Austria (http://www.congrex.ch/2005/ens/2005/)</p>	24	<p>This exhibit is confusing and irrelevant to the trial as instituted. PO has failed to explain why the exhibit is being relied upon. Further, the supplied URL link is defective.</p> <p>FRE 401 (Relevance “has any tendency to make a fact more or less probable than it would be without the evidence” and “is of consequence in determining the action”). FRE 402 (Irrelevant evidence is not admissible) FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)</p>
2007	<p>Scientific Program from Fifteenth Meeting of the European Neurological Society, June 18-22, 2005 (http://registration.akm.ch/einsicht.php?XNKONGRESS_ID=18&XNSPRACHE_ID=2)</p>	24	<p>This exhibit is confusing and irrelevant to the trial as instituted. PO has failed to explain why the exhibit is being relied upon.</p> <p>FRE 401 (Relevance “has any tendency to make a fact more or less probable than it would be without the</p>

			evidence” and “is of consequence in determining the action”). FRE 402 (Irrelevant evidence is not admissible) FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)
2008	Program from Wednesday, June 22, 2005 from Fifteenth Meeting of the European Neurological Society (http://registration.akm.ch/einsicht.php?XNKONGRESS_ID=18&XNSPRACHE_ID=2&XNMASKEN_ID=200&XSDATUM=2005-06-20)	24	This exhibit is confusing and irrelevant to the trial as instituted. PO has failed to explain why the exhibit is being relied upon. FRE 401 (Relevance “has any tendency to make a fact more or less probable than it would be without the evidence” and “is of consequence in determining the action”). FRE 402 (Irrelevant evidence is not admissible) FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)
2011	Declaration of Richard A. Rudick, M.D. Under 37 C.F.R. §1.132 filed on August 3, 2012 in U.S. Patent Application No. 13/372,426	31-38	To the extent the document is relied upon for secondary considerations of non-obviousness, there is no nexus to the claimed methods. The unexpected results evidence presented in an ex parte examination is not binding in a subsequent

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