

For the Petitioner

Paper No. \_\_\_\_

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Carmichael IP, PLLC

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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 SPANGENBERG,  
Petitioners,

v.

BIOGEN MA INC.,  
Patent Owner.

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Case IPR2015-01993

Patent 8,399,514 B2

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**PETITIONER 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 Biogen’s Opposition to the Petition (Paper 38), Patent Owner’s Motion to Antedate (Paper 40), O’Neill Declaration II (Ex. 2076), Dawson Declaration (Ex. 2077), Lansden Declaration (Ex. 2079), and Sarnelli Declaration (Ex. 2080). 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	Cited at	Objection(s)
2031	<i>Biogen Idec Announces Positive Top Line Results from the First Phase 3 Trial Investigating Oral BG-12 (DIMETHYL FUMARATE) in Multiple Sclerosis</i> , BIOGEN MEDIA (Apr. 11, 2011, 7:00 AM EDT), <a href="http://media.biogen.com/press-release/multiple-sclerosis-ms/biogen-idec-announces-positivetop-">http://media.biogen.com/press-release/multiple-sclerosis-ms/biogen-idec-announces-positivetop-</a>	O’Neill Dec. II (Ex. 2076) at ¶43	This exhibit is confusing, lacks authentication, is not available at the cited url location, and constitutes and/or contains hearsay. FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons) FRE 801(c) (hearsay) FRE 802 (not an exception to the rule against hearsay) FRE 901 (lacking authentication)

	line-results-first-phase-3-tr		FRE 902 (evidence is not self-authenticating)
2033	Daily Dosing Date Ranges Chart	Motion to Antedate, Paper 40 at 9, 13 and 14.	It is unclear what “a given range” is and how it relates to the claimed invention for any of the six studies, including one human clinical. Exs. 2375 and 2092, at the pages cited in the chart, fail to describe the asserted start and end dates of study C-1900. FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)
2051	Biogen’s Daily Diligence Chart	Motion to Antedate, Paper 40 at 8.	This exhibit is confusing, lacks authentication and constitutes and/or contains hearsay. Hearsay under FRE 801(c). FRE 802 (not an exception to the rule against hearsay) FRE 803(6) (document has not been shown to be a business record “by the testimony of the custodian or another qualified witness”) FRE 807 (no required showing of residual exception requirements) FRE 901 (lacking authentication)

			FRE 902 (evidence is not self-authenticating)
2052	BG-12 Program Chart	Motion to Antedate, Paper 40 at 9-11.	This exhibit is confusing, lacks authentication and constitutes and/or contains hearsay. Hearsay under FRE 801(c). FRE 802 (not an exception to the rule against hearsay) FRE 803(6) (document has not been shown to be a business record “by the testimony of the custodian or another qualified witness”) FRE 807 (no required showing of residual exception requirements) FRE 901 (lacking authentication) FRE 902 (evidence is not self-authenticating)
2075	Bill Berkrot, <i>Biogen Profit Beats Estimates, Raises 2013 Forecast</i> , REUTERS (Apr. 25, 2013, 10:08 AM EDT), <a href="http://www.reuters.com/article/us-biogenidec-resultsidUSBRE9300Q920130425">http://www.reuters.com/article/us-biogenidec-resultsidUSBRE9300Q920130425</a>	Biogen’s Opposition to the Petition, Paper 38 at 54.	This exhibit lacks authentication and constitutes and/or contains hearsay. Hearsay under FRE 801(c). FRE 802 (not an exception to the rule against hearsay) FRE 901 (lacking authentication) FRE 902 (evidence is not self-authenticating)
2081	<i>New Data Show Strong, Sustained</i>	Biogen’s Opposition to the	This exhibit is confusing, lacks authentication, is

	<p><i>Effects of          TECFIDERA®          (Dimethyl Fumarate)          in Newly-Diagnosed          and Early Disease          Course Multiple          Sclerosis Patients,</i>          BIOGEN MEDIA (Oct. 7,          2015, 6:00 AM EDT),  <a href="http://media.biogen.com/pressrelease/neurology/new-data-show-strong-sustained-effectstecfidera-dimethyl-fumarate-newly-dia">http://media.biogen.com/pressrelease/neurology/new-data-show-strong-sustained-effectstecfidera-dimethyl-fumarate-newly-dia</a></p>	<p>Petition, Paper 38          at 64.</p>	<p>not available at the cited url location, and constitutes and/or contains hearsay.          FRE 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons)          FRE 901 (lacking authentication)          FRE 902 (evidence is not self-authenticating)          FRE 801(c) (hearsay)          FRE 802 (not an exception to the rule against hearsay)</p>
<p>2082</p>	<p>Excerpts from Clinical Study Report Study Number: 109MS301 (Report Date: 1/14/2012)</p>	<p>O’Neill Dec. II (Ex. 2076) at ¶¶9 and 40;          Dawson Dec. (Ex. 2077) at ¶¶ 6, 7 and 31.</p>	<p>Hearsay under FRE 801(c).          FRE 802 (not an exception to the rule against hearsay)          FRE 803(6) (document has not been shown to be a business record “by the testimony of the custodian or another qualified witness”)          FRE 807 (no required showing of residual exception requirements)          FRE 901 (lacking authentication)          FRE 902 (evidence is not self-authenticating)</p>

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