

For the Petitioner

Paper No. \_\_

Lead counsel: Robert W. Hahl, Reg. No. 33,893

Backup counsel: Robert Mihail, Reg. No. 66,021

Backup counsel: John K. Pike, Reg. No. 41,253

Neifeld IP Law, PC

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

Petitioner

v.

Biogen MA Inc.

Patent Owner

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Case IPR2015-01993

Patent 8,399,514

Title: TREATMENT FOR MULTIPLE SCLEROSIS

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**PETITIONER'S EXHIBIT LIST**

**37 CFR 42.63(e) states that:**

(e) *Exhibit list.* Each party must maintain an exhibit list with the exhibit number and a brief description of each exhibit. If the exhibit is not filed, the exhibit list should note that fact. A current exhibit list must be served whenever evidence is served and the current exhibit list must be filed when filing exhibits.

**Description of Marks in the Date Served, and Date Filed columns:**

A date in the "Date Served" column indicates the exhibit has been served on the specified date.

A date in the "Date Filed" column indicates the exhibit has been filed on the specified date.

| Exhibit Number | Description of Exhibit  | Date Served | Date Filed |
|----------------|---|-------------|------------|
| 1001           | US Patent No. 8,399,514, titled "Treatment for Multiple Sclerosis" to Lukashev et al. ('514 patent).                                  | 9/28/2015   | 9/28/2015  |
| 1002           | Wakkee M et al., "Drug evaluation: BG-12, an immunomodulatory dimethylfumarate." Curr. Opin. Investig. Drugs. 2007 Nov; 8(11):955-62. | 9/28/2015   | 9/28/2015  |

| Exhibit Number | Description of Exhibit  | Date Served | Date Filed |
|----------------|---|-------------|------------|
| 1003           | Kappos et al., “Efficacy of a novel single-agent fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase 2 study”, J Neurol (2006) 253 [Suppl 2]: II/1–II/170; pg. II/27 O108.   | 9/28/2015   | 9/28/2015  |
| 1004           | International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Dose-Response Information to Support Drug Registration E4, Current Step 4 version, dated 10 March 1994. | 9/28/2015   | 9/28/2015  |
| 1005           | Declaration of Dr. Steven E. Linberg.   | 9/28/2015   | 9/28/2015  |
| 1006           | European Medicines Agency, Assessment Report, Tecfidera, 26 November 2013.  | 9/28/2015   | 9/28/2015  |

| Exhibit Number | Description of Exhibit   | Date Served | Date Filed |
|----------------|--|-------------|------------|
| 1007           | “Preliminary Amendment Under 37 C.F.R. § 1.115, In re application of: LUKASHEV et al.”, Application No. 13/372,426 that issued into US Patent 8,399,514. | 9/28/2015   | 9/28/2015  |
| 1008           | “Amendment and Reply Under 37 C.E.R. § 1.111, In re application of: LUKASHEV et al., Appl. No. 13/372,426” that issued into US Patent 8,399,514.         | 9/28/2015   | 9/28/2015  |
| 1009           | Office Action with mail date of 05/03/2012 for Application No. 13/372,426 that issued into US Patent 8,399,514.  | 9/28/2015   | 9/28/2015  |
| 1010           | Paper 178, Interference 106,023.   | 9/28/2015   | 9/28/2015  |
| 1011           | PCT Application No. PCT/US2008/001602  | 9/28/2015   | 9/28/2015  |
| 1012           | Certified copy of US Provisional Application No. 601888,921.   | 9/28/2015   | 9/28/2015  |

| Exhibit Number | Description of Exhibit   | Date Served | Date Filed |
|----------------|--|-------------|------------|
| 1013           | Assignment Record for US Patent No. 8,399,514 from USPTO's Assignments on the Web.   | 9/28/2015   | 9/28/2015  |
| 1014           | Paper 179, Interference 106,023.   | 9/28/2015   | 9/28/2015  |
| 1015           | Unassigned.  |             |            |
| 1016           | D. Werdenberg, et al., "Presystemic Metabolism and Intestinal Absorption of Antipsoriatic Fumaric Acid Esters", 2003, BIOPHARMACEUTICS & DRUG DISPOSITION, Biopharm. Drug Dispos. 24: 259-273 (2003), Published online in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/bdd.364. | 9/28/2015   | 9/28/2015  |
| 1017           | CV of Dr. Steven E. Linberg  | 9/28/2015   | 9/28/2015  |

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