

For the Patent Owner
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Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition For Affordable Drugs V LLC

Petitioner

v.

Biogen MA Inc.

Patent Owner

Case: IPR2015-01136

Patent 8,399,514

Title: TREATMENT FOR MULTIPLE SCLEROSIS

First Amended Petition

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Alexandria, VA 22313-14**

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A. Ground 1: Claims 1-20 would have been obvious over *Kappos 2005* (**Ex. 1003A**) or *ClinicalTrials NCT00168701* (**Ex. 1022A**) or ‘514 Patent admission of prior art in view of *ICH Guideline E4* (**Ex. 1004A**)16

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LIST OF EXHIBITS

- Exhibit 1001A US Patent No. 8,399,514, titled “Treatment for Multiple Sclerosis” to Lukashev et al. (‘514 patent)
- Exhibit 1002 Unassigned
- Exhibit 1003A Kappos et al., “A randomised, placebo-controlled phase II trial of a novel oral single-agent fumarate therapy, BG00012, in patients with relapsing-remitting multiple sclerosis”, 2005, *J Neurol* (2005) 252 [Suppl 2]: II/95–II/170, pII/148, P574.
- Exhibit 1004A 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.
- Exhibit 1005A Declaration of Dr. Steven E. Linberg.
- Exhibit 1006 Unassigned
- Exhibit 1007A “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.

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