

For the Patent Owner
Backup counsel: Robert W. Hahl, Reg. No. 33,893
Backup counsel: Robert Mihail, Reg. No. 66,021
Neifeld IP Law, PC

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

**Mail Stop PATENT BOARD
U.S. Patent Trial & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-14**

TABLE OF CONTENTS

I. INTRODUCTION1

II. MANDATORY NOTICES1

A. Real Party-In-Interest 37 C.F.R. § 42.8(b)(1)1

B. Related Matters 37 C.F.R. § 42.8(b)(2).....3

C. Designation of Lead and Backup Counsel 37 C.F.R. § 42.8(b)(3).....3

D. Notice of Service Information (37 C.F.R. § 42.8(b)(4))3

III. FEES 37 C.F.R. § 42.15(a)3

IV. REQUIREMENTS UNDER 37 C.F.R. § 42.104.....4

A. Grounds for Standing 37 C.F.R. § 42.104(a)4

B. Challenge and Precise Relief Requested 37 C.F.R. § 42.104(b)4

V. UNPATENTABILITY OF THE '514 PATENT7

A. Prosecution History of the '514 Patent7

B. The Effective Filing Date of U.S. 8,399,51410

C. Brief overview of the '514 Patent11

D. Person of Ordinary Skill in the Art13

E. Claim Construction.....14

F. Overview of Prior Art Reviewed by Dr. Linberg15

VI. DETAILED EXPLANATION OF THE CHALLENGES.....16

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

VII. CONCLUSION51

TABLE OF AUTHORITIES

Cases

Bettcher Indus., Inc. v. Bunzl USA, Inc., 661 F.3d 629 (Fed. Cir. 2011).....43

KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007)17

PAR Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186 (Fed. Cir. 2014).....43

Statutes

35 U.S.C. § 102.....4, 5

35 U.S.C. § 103.....6

Rules

37 C.F.R. § 42.8.....1, 3

37 C.F.R. § 42.15.....4

37 C.F.R. § 42.22.....7

37 C.F.R. § 42.100.....1

37 C.F.R. § 42.104.....4, 6

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.