

For the Petitioner  
Backup 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

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

---

**Petitioner's Request for Rehearing under 37 C.F.R. § 42.71(c)**

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

**Table of Contents**

**I. INTRODUCTION .....1**

**II. APPLICABLE LEGAL STANDARDS.....1**

    A. Standards Applicable to a Request for Rehearing..... 1

    B. Standard Applicable to Instituting an Inter Partes Review .....2

**III. BASIS FOR RELIEF REQUESTED .....2**

    A. The *Kappos* 2005 Publication ..... 2

    B. The ClinicalTrials publication.....9

    C. The ‘514 patent admission that DMF was known to be therapeutically  
active on MS ..... 10

    D. The Drugs R&D publication ..... 13

**IV. CONCLUSION .....15**

## Table of Authorities

### Cases

<i>In re O’Farrell</i> , 853 F.2d 894, 903 (Fed. Cir. 1988).....	7
<i>In re Kubin</i> , 561 F.3d 1351, 1360 (Fed. Cir. 2009).....	7
<i>In re Montgomery</i> , 677 F.3d 1375, 1382-1383 (Fed. Cir. 2012).....	6, 7
<i>Intri-Plex Technologies, Inc. and MMI Holdings, Ltd. v. Saint-Gobain Performance Plastics Rencol Limited</i> , IPR2014-00309, Paper 83, (PTAB 2014).....	12
<i>Mems Tech. Berhad v. ITC</i> , 447 Fed. Appx. 142, 162 (Fed. Cir. 2011).....	2, 9

### Statutes

35 U.S.C. § 102.....	2, 3, 9, 13
35 U.S.C. § 103.....	1
35 U.S.C. § 314.....	2

### Regulations

37 C.F.R. § 42.71.....	1
37 C.F.R. § 42.108.....	1, 2

## I. INTRODUCTION

On September 2, 2015, the Board issued a Decision under 37 C.F.R. § 42.108 (“Decision”) denying institution of *Inter Partes* Review of U.S. Patent 8,399,514 (‘514 patent) on three (3) challenges raised by Petitioner in an amended Petition (“Petition”). The challenges as stated on page 5 of the Decision are:

Challenge No.	Claims	35 U.S.C.	Prior art forming basis of challenge
1	1–20	§ 103(a)	Kappos and ICH Guideline
2	1-20	§ 103(a)	ClinicalTrials and ICH Guideline
3	1-20	§ 103(a)	Prior art admissions and ICH Guideline

This Request for Rehearing (“Request”) seeks reconsideration of challenges 1, 2 and 3.

This Request is authorized under 37 C.F.R. § 42.71(c). Prior authorization of the Board is not required. 37 C.F.R. §42.71(d). As this Request is being filed within 30 days of the entry of a decision not to institute a trial, 37 C.F.R. § 42.71 (d)(2), this Request is being timely filed.

## II. APPLICABLE LEGAL STANDARDS

Petitioner urges that the Decision misapprehended or overlooked the following:

### A. Standards Applicable to a Request for Rehearing

Under the APA, the Federal Circuit stated that "[a]n abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors." *Mems Tech. Berhad v. ITC*, 447 Fed. App'x. 142, 162 (Fed. Cir. 2011) citing *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005).

### **B. Standard Applicable to Instituting an Inter Partes Review**

Under 35 U.S.C. § 314(a), as implemented by 37 C.F.R. § 42.108, an *inter partes* review will only be instituted for a ground of unpatentability where the Board decides that "the petition supporting the ground would demonstrate that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable."

## **III. BASIS FOR RELIEF REQUESTED**

Petitioner urges that the Decision misapprehended or overlooked the following:

### **A. The *Kappos* 2005 Publication**

On pages 9 and 10 of the Decision, the Board declined "to find that *Kappos* describes the use of DMF as a compound useful for treating multiple sclerosis" and gives four separate reasons for its decision.

In relying on its first reason, the Decision, on page 9, overlooks or misapprehends that *Kappos* 2005 is **itself** a 102(b) printed publication which

# 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.