

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 B2

Before FRED E. McKELVEY, SALLY GARDNER LANE, and
DEBORAH KATZ, *Administrative Patent Judges*.

McKELVEY, *Administrative Patent Judge*

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. Introduction

Pending before the Board is Petitioner's First Amended Petition¹ ("Pet.") (Paper 9) seeking entry of an order instituting an *inter partes* review.

Patent Owner timely filed a Preliminary Response. ("Prelim. Resp.") (Paper 21).

II. Background

A. Parties

Petitioner is Coalition for Affordable Drugs V LLC along with ten other entities.² Pet. 1–2.

Patent Owner is Biogen MA Inc. Prelim. Resp. 1.

B. Involved Patent

The involved patent is U.S. Patent 8,399,514 B2 ("the '514 Patent") issued 19 March 2013. Ex. 1001A.

¹ An earlier version of the Petition appears in the record. *See* Paper 2 (1 May 2015). We have considered only the First Amended Petition (Paper 9, filed 27 May 2015) in resolving whether to institute an *inter partes* review trial.

² The ten other entities are identified as:

- (1) Hayman Credes Master Fund, L.P. ("Credes"),
- (2) Hayman Orange Fund SPC ("HOF"),
- (3) Hayman Capital Master Fund, L.P. ("HCMF"),
- (4) Hayman Capital Management, L.P. ("HCM"),
- (5) Hayman Offshore Management, Inc. ("HOM"),
- (6) Hayman Investments, L.L.C. ("HI"),
- (7) nXn Partners, LLC ("nXnP"),
- (8) IP Navigation Group, LLC ("IPNav"),
- (9) J. Kyle Bass, and
- (10) Erich Spangenberg.

The application which matured into the '514 Patent was filed on 13 February 2012. Ex. 1001A, 1 (22).

The '514 Patent claims priority based on several applications; the earliest of which was filed on 8 February 2007. *Id.* (60).

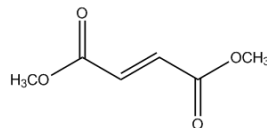
The '514 Patent contains claims 1–20. Ex. 1001A, cols. 27–30.

Petitioner challenges all of the claims, *viz.*, claims 1–20. Pet. 1:2–4.

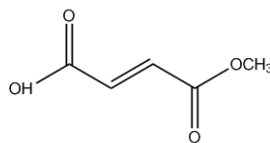
C. Abbreviations

DMF	Dimethyl fumarate ³
EDSS	Expanded disability status scale—mentioned in Kappos
MMF	Monomethyl fumarate ⁴
MRI	Magnetic resonance imaging—mentioned in Kappos
MS	Multiple sclerosis
PO	Per os (by mouth or orally)
RRMS	Relapsing-remitting multiple sclerosis—mentioned in Kappos

³ The structural formula for DMF is:



⁴ The structural formula for MMF is:



D. Prior art

The prior art relied upon is:

Kappos et al. “Kappos”	J. Neurol. (2005) 252 [Suppl. 2]: <i>A Randomized, placebo- controlled phase II trial of a novel oral single-agent fumarate therapy, BG00012, in patients with relapsing- remitting multiple sclerosis</i>	2005	Ex. 1003A
ICH Guideline	<i>Dose-Response Information to Support Drug Registration E4</i>	10 Mar. 1994	Ex. 1004A
ClinicalTrials NCT00168701 “ClinicalTrials”	<i>Double-Blind, Placebo- Controlled, Dose- Ranging Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing- Remitting Multiple Sclerosis</i>	Dated: 14 Sept. 2005, identified as downloaded from ClinicalTrials.gov archive, U.S. National Institutes of Health	Ex. 1022A

In addition, Petitioner relies on what it characterizes as an “admission of prior art” and specifically a statement in the written descriptive portion of the Specification of the ’514 patent. Ex. 1001A, col. 5:6–7: “Fumaric acid

esters, such as DMF [dimethyl fumarate], have been proposed for treatment of MS [multiple sclerosis]” (Pet., page 6:4–5), citing (Ex. 1001A, col. 5:7), *inter alia*, BG 12, 6 Drugs R&D 229–30 (2005) (Ex. 1021A).

E. Related Proceeding

The ’514 Patent is also involved in *Biogen MA Inc. v. Forward Pharma AS*, Interference 106,023 (PTAB Declared 13 Apr. 2015) (Interference 106,023, Paper 1).

In the interference, Forward Pharma was authorized to file, and has filed, Forward Pharma Motion 7 seeking entry of a judgment against Biogen alleging that the claims of the ’514 Patent are unpatentable under 35 U.S.C. § 103(a) over the prior art. Interference 106,023, Paper 167. An Opposition to the Motion has not yet been filed.

In determining whether to institute a trial in this IPR, we have *not* considered any of the evidence offered, or arguments made, by Forward Pharma in support of its Motion 7.

F. Challenges

While Petitioner mentions only a “Ground 1,” there are in fact three challenges—which we identify as Challenges 1–3. Pet. 6.

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

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