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Paper 23
Entered: September 2, 2015

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 Petition[1] ("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.

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[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).

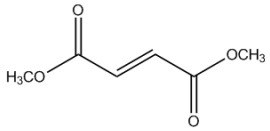
The '514 Patent contains claims 1–20. Ex. 1001A, cols. 27–30.

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

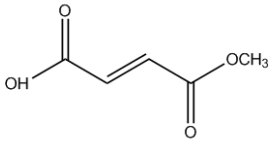
C. Abbreviations

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]:A *Randomized, placebo-controlled phase II trial of a novel oral single-agent fumarate therapy, BG00012, in patients with relapsing-remitting multiple sclerosis*	2005	Ex. 1003A
ICH Guideline	*Dose-Response Information to Support Drug Registration E4*	10 Mar. 1994	Ex. 1004A
ClinicalTrials NCT00168701 "ClinicalTrials"	*Double-Blind, Placebo-Controlled, Dose-Ranging Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis*	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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