

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
HAYMAN ORANGE FUND SPC – PORTFOLIO A;
HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS, and ERICH SPANGENBERG,
Petitioners,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

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

McKELVEY, *Administrative Patent Judge*.

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

I. Introduction

A. Background

A second petition seeking to institute an *inter partes* review in connection with U.S. Patent No. 8,399,514 B2 (“’514 patent”) is before the Board. Paper 1.

A first petition seeking to institute an *inter partes* review was denied. *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01136, 2015 WL 5169256 (Paper 23) (PTAB Sept. 2, 2015), *reh’g denied*, IPR2015-01136 (Paper 29) (PTAB Oct. 23, 2015).

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

Patent Owner timely filed a Preliminary Response. Paper 11.

Petitioner was invited to file a Reply. Paper 13.

Petitioner timely filed the Reply.¹ Paper 17.

B. The Parties

Petitioner is:

- (1) Coalition for Affordable Drugs V LLC,
- (2) Hayman Credes Master Fund, L.P.,

¹ The Reply is styled REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE IN SUPPORT OF PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 8,399,514 UNDER 35 U.S.C. §§ 311-319. In the future the style of any paper filed in this IPR shall not exceed one line. A more appropriate style would have been REPLY TO PRELIMINARY RESPONSE. Use of a single line renders entry of papers into Board data records much easier. Failure to adhere to the one-line rule established in this IPR may result in a paper being expunged.

- (3) Hayman Orange Fund SPC – Portfolio A,
- (4) Hayman Capital Master Fund, L.P.,
- (5) Hayman Capital Management, L.P.,
- (6) Hayman Offshore Management, Inc.,
- (7) Hayman Investment, LLC,
- (8) NXN Partners, LLC,
- (9) IP Navigation Group, LLC,
- (10) J. Kyle Bass, and
- (11) Erich Spangenberg.

Paper 1, pages 1–2.

Patent Owner is Biogen MA Inc. Paper 11, page 1.

C. Abbreviations

BG00012 or BG12	Dimethyl fumarate
DMF	Dimethyl fumarate
ICH	International Conference on Harmonisation
MMF	Monomethyl fumarate
MRI	Magnetic resonance imaging
RRMS	Relapsing-remitting multiple sclerosis

D. Evidence Relied Upon²

The following evidence is relied upon in support of the Petition:

Name	Exhibit No.	Description	Date
Kappos 2006	1003	<i>Efficacy of a Novel Oral Single-Agent Fumarate, BG00012, in Patients with Relapsing-Remitting Multiple Sclerosis: Results of a Phase 2 Study</i> , J. NEUROL (2006) 253 (SUPPL 2); II/1–II/170, page II27	May 2006
<p>Kappos 2006 is prior art under 35 U.S.C. § 102(b) based on the filing date of Biogen’s PCT application (7 February 2008). If Biogen is entitled to a benefit date of its Provisional Application (8 February 2007), Kappos 2006 is prior art under 35 U.S.C. § 102(a). Further discussion of Kappos 2006 occurs later in this opinion.</p>			
Clinical Trials	1022	<i>Double-Blind, Placebo-Controlled, Dose-Ranging Study to Determine the Efficacy and Safety of BG00012 in Subjects with Relapsing-Remitting Multiple Sclerosis</i> , CLINICALTRIALS.GOV ARCHIVE	14 Sept. 2005
<p>Clinical Trials is prior art under 35 U.S.C. § 102(b).</p>			

² Because the application maturing into the ’514 patent was filed before the enactment of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011), we apply the pre-AIA version of 35 U.S.C. §§ 102, 103, 112, and 119.

Name	Exhibit No.	Description	Date
Joshi '999	1030	U.S. Patent 7,320,999 B2	22 Jan. 2008 filed 17 July 2002
Joshi '999 is prior art under 35 U.S.C. § 102(a) having issued prior to Biogen's PCT filing date (7 February 2008). If Biogen is entitled to a benefit date of its Provisional Application (8 February 2007), then Joshi '999 is prior art under 35 U.S.C. § 102(e) based on its filing date (17 July 2002).			
ICH Guideline	1004	<i>ICH Harmonised Tripartite Guideline, DOSE-RESPONSE INFORMATION TO SUPPORT DRUG REGISTRATION E4</i>	10 Mar. 1994
Joshi '992	1036	U.S. Patent 6,436,992 B1	20 Aug. 2002
Begleiter	1027	<i>Dietary Induction of NQO1 Increases the Antitumour Activity of Mitomycin C in Human Colon Tumours in vivo,</i> 91 BRITISH J. CANCER 1624–1631	2004
ICH Guideline, Joshi '992, and Begleiter are prior art under 35 U.S.C. § 102(b).			

E. Grounds of Unpatentability

Claims 1–20 appear in the '514 patent. Ex. 1001, col. 27:58 through col. 30:27.

The following grounds of unpatentability are urged in the Petition.

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