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,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case: IPR2015-01993
U.S. Patent No. 8,399,514

BIOGEN'S REPLY IN SUPPORT OF ITS MOTION TO ANTEDATE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Regulations

I. Introduction

Petitioner's reply to Biogen's Motion to Antedate rests on incorrect legal standards and thinly supported rebuttal testimony. The Board should conclude that Biogen is entitled to its priority date and has antedated Kappos 2006.

II. The Provisional Application Provides Written-Description Support for the '514 Patent Claims

Beginning in its first paragraph, the '921 provisional application states unequivocally that the invention relates in part to the "use of therapeutic compounds . . . for treating neurological diseases, including . . . multiple sclerosis." (**Ex. 1012** at ¶ [0001]; **Ex. 2046** ¶ 29; **Ex. 2384** at 103:25-104:16, 105:2-5.) The application further states that fumaric acid derivatives have been proposed for the treatment of MS and that, in some embodiments, the inventive treatment method involves administering a therapeutically effective amount of "a fumaric acid derivative (e.g., DMF or MMF)." (**Ex. 1012** at ¶¶ [0020], [0031], [0066].) The application then discloses that "an effective dose of DMF or MMR [sic, MMF] to be administered to a subject orally can be . . . from about 480 mg to about 720 mg per day." (*Id*. at ¶ [0116].) Dr. Wynn, an MS clinician with decades of experience, explains in his declaration why these and other disclosures in the provisional application provide written-description support for the claimed subject matter relating to a method of treating MS with a dose of about 480 mg/day of DMF,

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