

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: IPR2016-01993
U.S. Patent No. 8,399,514

DECLARATION OF DANIEL WYNN, M.D. FACNS FAASM

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PERSONAL BACKGROUND AND QUALIFICATIONS	3
III.	DOCUMENTS CONSIDERED	5
IV.	ISSUES ADDRESSED	6
V.	LEGAL PRINCIPLES.....	7
VI.	BIOGEN’S ’514 PATENT.....	8
VII.	LEVEL OF ORDINARY SKILL IN THE ART.....	14
VIII.	OPINIONS REGARDING DR. LINBERG’S PROPOSED LEVEL OF ORDINARY SKILL IN THE ART.....	15
IX.	BIOGEN’S ’921 PROVISIONAL DESCRIBES AND ENABLES ALL TWENTY CLAIMS IN THE ’514 PATENT.....	17
	A. The ’921 Provisional Provides Written Description Support for All of the ’514 Patent Claims.....	18
	B. The ’921 Provisional Enables the ’514 Patent Claims.....	26
X.	BIOGEN’S INTERNATIONAL PATENT APPLICATION NO. PCT/US2008/001602 DESCRIBES AND ENABLES ALL TWENTY CLAIMS IN THE ’514 PATENT	29
XI.	CONCLUSION.....	32

I, Daniel Wynn, provide the following testimony:

I. INTRODUCTION

1. I have been engaged by counsel for Biogen MA Inc., Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, as an expert consultant for this *inter partes* review proceeding. I am being compensated at a rate of \$1,000 per hour, plus reimbursement for related out-of-pocket expenditures. My compensation is not contingent upon my opinions or the outcome of this or any other proceeding.

2. I understand that the patent involved in this proceeding is U.S. Patent No. 8,399,514 (**Ex. 1001**, “the ’514 patent”), which is assigned on its face to Biogen Idec MA Inc., but is now assigned to Biogen MA Inc. (“Biogen”).

3. I have been informed that the ’514 patent issued from a series of applications as shown below:

Country	Patent No./ Application No.	Filing Date	Abbreviation
U.S.	13/372,426	Feb. 13, 2012	’426 Application
U.S.	12/526,296	Feb. 7, 2008	’296 Application
Int’l	PCT/US2008/001602	Feb. 7, 2008	’602 Application (“B2,” Ex. 1011)
U.S.	60/888,921	Feb. 8, 2007	’921 Provisional (“B1,” Ex. 1012)

4. I understand that the '602 Application, '296 Application, and '426 Application share a substantially identical written description.

5. Claim 1 of the '514 patent states:

A method of treating a subject in need of treatment for multiple sclerosis comprising

orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of

(a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and

(b) one or more pharmaceutically acceptable excipients,

wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

Claims 11, 15, and 20 describe additional methods of treating MS by administering about 480 mg per day of dimethyl fumarate (DMF), monomethyl fumarate (MMF), or a combination thereof. Claims 6 and 12 focus on administering DMF, while claim 7 provides for administering MMF. Claim 2 specifies that the pharmaceutical composition is administered in the form of a tablet, suspension, or capsule. Dependent claims 3-5, 9, 13, 14, and 16 further specify the frequency of

dosing, e.g., twice or three times a day. Claims 8 and 10 provide that the therapeutically effective dose is administered to the subject for at least 12 weeks. Claims 17-19 depend from claims 1, 11, and 15, respectively, and specify that the expression level of NQO1 is elevated after administering DMF, MMF, or a combination thereof.

II. PERSONAL BACKGROUND AND QUALIFICATIONS

6. I am the Director of Clinical Research and Director of the Multiple Sclerosis Center at Consultants in Neurology in Northbrook, Illinois. Consultants in Neurology is a large specialty practice focusing on the evaluation and treatment of multiple sclerosis and other neurological conditions. As Director of Clinical Research and Director of the Multiple Sclerosis Center, I supervise clinicians and oversee operations in the Multiple Sclerosis Center, train and manage research staff, and maintain an active clinical practice evaluating and treating patients where about 85% of my practice involves individuals with multiple sclerosis (MS). My current practice also includes continuous involvement in clinical trials, often as principal investigator, and research concerning the development of new therapeutics.

7. I received my medical doctorate from The Chicago Medical School and completed residencies in internal medicine and neurology at the Mayo

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.