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
Patent 8,399,514 B2

DECLARATION OF CARA LANSDEN

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TABLE OF ABBREVIATIONS/ACRONYMS

Abbreviation	Definition
AAN	American Academy of Neurology
AC	Advisory Committee
ACI	Applied Clinical Intelligence
ADCI	Accomplishments, Disappointments and Critical Issues
ADME	Absorption, Distribution, Metabolism, and Excretion
ADS	Application Data Sheet
AE	Adverse Event
ALT	Alanine Aminotransferase
AOB	Assignment of Benefit
API	Active Pharmaceutical Ingredient
ARR	Annualized Relapse Rate
AST	Aspartate Aminotransferase
BID	Twice-daily dosing
BIIB	Biogen Idec, Inc.
BLA	Biologics License Application
BP	Blood Pressure
C57BL/6	C57 Black 6
Cdr	Commander
CAC	Carcinogenicity Assessment Committee
CAPA	Corrective and Preventive Action
CCLS	Covance Central Laboratory Services SA
CCPA	Court of Customs and Patent Appeals
CFR	Code of Federal Regulations
CDER	Center for Drug Evaluation and Research
CDP	Clinical Development Plan
CDT	Clinical Development Team
CEC	Clinical Events Committee
CIOMS	Council for International Organizations of Medical Sciences
CMC	Chemistry, Manufacturing, and Controls
CPO	Country Pharma Organization
CR	Child Resistant
CRA	Clinical Research Associate
CRB	Clinical Review Board
CRF	Case Report Form

CRO	Contract Research Organization
CSC	Clinical Safety Committee
CSR	Clinical Study Report
CSSR	Clinical Site Status Report
CTRB	Clinical Trial Review Board
CTA	Clinical Trial Application
DART	Data Analysis and Review Team
DBL	Database Lock
DBRPCT	Double Blind Randomized Placebo-Controlled Trial
DCF	Data Correction Form
DCSI	Development Core Safety Information
DM	Data Management
DMF	Dimethyl Fumarate
DOC	Development Oversight Committee
DRG	Diagnosis Related Groups
DSMC	Data Safety Monitoring Committee
eCTD	Electronic Common Technical Document
Ex	Exhibit
EC	Ethics Commission
ECG/EKG	Electrocardiogram
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EDSS	Expanded Disability Status Scale
EMA	European Medicines Agency
EN	Examining Neurologist
EOP2	End of Phase II
EQ-5D	European Quality of Life - Dimensions Health Survey
ERT	*e*Research Technology
EU	European Union
FDA	Food and Drug Administration
FDF	Financial Disclosure Form
FP	Forward Pharma
FPI	First Patient In
Gd	Gadolinium
GA	Glatiramer Acetate
GI	Gastrointestinal
GMP	Good Manufacturing Practice
HBsAg	Hepatitis B Surface Antigen

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HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HV	Healthy Volunteers
Hx	Medical History
IB	Investigator's Brochure
ICF	Informed Consent Form
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drug Application
INEC	Independent Neurology Evaluation Committee
IP	Investigational Product
ISE	Integrated Summary of Effectiveness
ISS	Integrated Summary of Safety
IXRS	Interactive Voice Response System
kg	kilogram
LFT	Liver Function Test
LPO	Last Patient Out
m^2	meters squared
mg	milligram
MHRA	Medicines and Healthcare Products Regulatory Agency
MMF	Monomethyl Fumarate
MPR	Medication Possession Ratio
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
MSFC	Multiple Sclerosis Functional Composite
MTD	Maximum Tolerated Dose
MTR	Magnetization Transfer Ratio
NDA	New Drug Application
NHP	Non-Human Primate
NOAEL	No Observable Adverse Effects Level
ODMP	Ongoing Data Management Plan
p53	Tumor Protein p53
PCT	Patent Cooperation Treaty
PD	Protocol Deviation
PIND	Pre-Investigational New Drug Application
PK	Pharmacokinetics
PMDA	Pharmaceuticals and Medical Devices Agency
PRA	Pharmaceutical Research Associates

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