

Table of Contents For Ex. 1007A

Amendment -----	pages 2 - 13
Exhibit 1 (Declaration of Katherine T. Dawson, M.D. Under 37 C.F.R. § 1.132) -----	pages 14 – 35
Exhibit A (Curriculum Vitae for Katherine T. Dawson -----	pages 38 - 43
Exhibit B (Kappos, L., et al., "Efficacy and safety of oral fumarate in patients with relapsing-remitting multiple sclerosis: a multicenter, randomised, double--blind, placebo--controlled phase IIIb study," Lancet 372: 1463-72 (2008) -----	pages 44 - 54
Exhibit C (Kappos, L., et al., "Efficacy of a novel oral single-agent fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase 2 study* 16th Meeting of the European Neurological Society (May 30, 2006) (Slide Presentation)) -----	pages 56 - 57
Exhibit D (Kappos, L., et al., "Efficacy of a novel oral single-agent Fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase II study," 16th Meeting of the European Neurological Society (May 30, 2006) (Abstract to the Presentation) -----	pages 78 - 79
Exhibit E ("Oral Compound BG-12 Achieves Primary Endpoint in Phase II Study of Relapsing-Remitting MS with BG-12 Led to Statistically Significant Reductions in MRI Measures," Biogen Idec News Release (May 30, 2006)) -----	pages 80 - 82
Exhibit 2 (Press Release Details) -----	pages 83 - 86
Transmittal letter -----	page 87

Biogen Exhibit 2015
Mylan v. Biogen
IPR2018-01403
Coalition Exhibit 1007A
Coalition v. Biogen
IPR2015-01136

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LUKASHEV *et al.*

Appl. No.: *To be assigned*

(Continuation of Appl. No. 12/526,296,

§ 371(c) Date: January 13, 2011)

Filing Date: Herewith

For: **Treatment for Multiple Sclerosis
(As Amended)**

Confirmation No.: *To be assigned*

Art Unit: *To be assigned*

Examiner: *To be assigned*

Atty. Docket: 2159.3210002/JMC/MRG/U-S

Preliminary Amendment Under 37 C.F.R. § 1.115

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In advance of prosecution, Applicants submit the following amendments and remarks.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks and Arguments begin on page 6 of this paper.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Specification

Please amend the title as follows:

~~Treatment for Multiple Sclerosis NRF2 screening assays and related methods and compositions~~

Please amend paragraph [0128], beginning on page 33, line 21, as follows:

[0128] Immunohistochemistry was performed using the Dakoautostainer as follows. Endogenous peroxidase was quenched by a 10 minute incubation in 3% H₂O₂ / Methanol. The rabbit anti Nrf2 antibody C-20 (sc-722, Santa Cruz Biotechnology) was added at a 1:250 dilution in Dako Diluent with Background Reducing Components (Dako # S3022) C-20 antibody was detected using the Envision anti rabbit labeled polymer-HRP (Dako #K4003) and DAB (Vector Labs #SK-4100) was used as the chromogenic substrate. Morphometric analysis of Nrf2 immunostaining was performed using ImageJ software from NIH (<http://rsb.info.nih.gov/ij/>).

On page 1, below the title of the invention, please add the following new paragraph:

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application No. 12/526,296, § 371(c) Date January 13, 2011, now pending, which is the U.S. National Phase of International Application No. PCT/US2008/001602, filed February 7, 2008, which claims the benefit of U.S. Provisional Application 60/888,921, filed February 8, 2007.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

- 1-17. (Cancelled)
18. (New) 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.
19. (New) The method of claim 18, wherein the pharmaceutical composition is administered in the form of a tablet, a suspension, or a capsule.
20. (New) The method of claim 18, wherein the therapeutically effective amount is administered in separate administrations of 2, 3, 4, or 6 equal doses.
21. (New) The method of claim 20, wherein the therapeutically effective amount is administered in separate administrations of 2 equal doses.
22. (New) The method of claim 20, wherein the therapeutically effective amount is administered in separate administrations of 3 equal doses.
23. (New) The method of claim 18, wherein the pharmaceutical composition consists essentially of dimethyl fumarate and one or more pharmaceutically acceptable excipients.

24. (New) The method of claim 18, wherein the pharmaceutical composition consists essentially of monomethyl fumarate and one or more pharmaceutically acceptable excipients.
25. (New) The method of claim 18, wherein the pharmaceutical composition is administered to the subject for at least 12 weeks.
26. (New) The method of claim 23, wherein the therapeutically effective amount is administered to the subject in 2 equal doses.
27. (New) The method of claim 26, wherein the therapeutically effective amount is administered to the subject for at least 12 weeks.
28. (New) A method of treating a subject in need of treatment for multiple sclerosis consisting essentially of orally administering to the subject about 480 mg per day of dimethyl fumarate, monomethyl fumarate, or a combination thereof.
29. (New) The method of claim 28, wherein about 480 mg of dimethyl fumarate per day is administered to the subject.
30. (New) The method of claim 29, wherein the dimethyl fumarate is administered in separate administrations of 2 equal doses.
31. (New) The method of claim 29, wherein the dimethyl fumarate is administered in separate administrations of 3 equal doses.
32. (New) A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject a pharmaceutical composition consisting essentially of (a) a therapeutically effective amount of dimethyl fumarate and (b) one or more pharmaceutically acceptable excipients, wherein

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.