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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)

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

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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% H<sub>2</sub>O<sub>2</sub> / 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

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