

**Reply Under 37 C.F.R. § 1.116
Prioritized Examination (Track 1) – Art Unit 1649**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LUKASHEV *et al.*

Appl. No.: 13/372,426

Filed: February 13, 2012

For: **Treatment for Multiple Sclerosis**

Confirmation No.: 5998

Art Unit: 1649

Examiner: ULM, John D.

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

Reply to Final Office Action Under 37 C.F.R. § 1.116

Mail Stop AF

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

Commissioner:

In reply to the Final Office Action dated October 12, 2012 (“the Final Office Action”), Applicants submit the following Remarks.

The Claims are listed beginning on page 2 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.

Listing of the Claims

The claims are listed below for the Examiner's convenience.

- 1-17. (Cancelled)
18. (Previously Presented) 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. (Previously Presented) The method of claim 18, wherein the pharmaceutical composition is administered in the form of a tablet, a suspension, or a capsule.
20. (Previously Presented) The method of claim 18, wherein the therapeutically effective amount is administered in separate administrations of 2, 3, 4, or 6 equal doses.
21. (Previously Presented) The method of claim 20, wherein the therapeutically effective amount is administered in separate administrations of 2 equal doses.
22. (Previously Presented) The method of claim 20, wherein the therapeutically effective amount is administered in separate administrations of 3 equal doses.

23. (Previously Presented) The method of claim 18, wherein the pharmaceutical composition consists essentially of dimethyl fumarate and one or more pharmaceutically acceptable excipients.
24. (Previously Presented) The method of claim 18, wherein the pharmaceutical composition consists essentially of monomethyl fumarate and one or more pharmaceutically acceptable excipients.
25. (Previously Presented) The method of claim 18, wherein the pharmaceutical composition is administered to the subject for at least 12 weeks.
26. (Previously Presented) The method of claim 23, wherein the therapeutically effective amount is administered to the subject in 2 equal doses.
27. (Previously Presented) The method of claim 26, wherein the therapeutically effective amount is administered to the subject for at least 12 weeks.
28. (Previously Presented) 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. (Previously Presented) The method of claim 28, wherein about 480 mg of dimethyl fumarate per day is administered to the subject.
30. (Previously Presented) The method of claim 29, wherein the dimethyl fumarate is administered in separate administrations of 2 equal doses.

Reply to Final Office Action of October 12, 2012

31. (Previously Presented) The method of claim 29, wherein the dimethyl fumarate is administered in separate administrations of 3 equal doses.
32. (Previously Presented) 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 the therapeutically effective amount of dimethyl fumarate is about 480 mg per day.
33. (Previously Presented) The method of claim 32, wherein the dimethyl fumarate is administered in separate administrations of 2 equal doses.
34. (Previously Presented) The method of claim 18, wherein the expression level of NQO1 in the subject is elevated after administering to the subject the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof.
35. (Previously Presented) The method of claim 28, wherein the expression level of NQO1 in the subject is elevated after administering to the subject about 480 mg per day of dimethyl fumarate, monomethyl fumarate, or a combination thereof.
36. (Previously Presented) The method of claim 32, wherein the expression level of NQO1 in the subject is elevated after administering to the subject the therapeutically effective amount of dimethyl fumarate.

Atty. Dkt. No. 2159.3210002/JMC/MRG/U-S

37. (Previously Presented) A method of treating a subject in need of treatment for multiple sclerosis comprising treating the subject in need thereof with a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 mg per day.

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.