

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LUKASHEV, Matvey E.

Appl. No.: 12/526,296

§ 371(c) Date: January 13, 2011

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

Confirmation No.: 5197

Art Unit: 1614

Examiner: Ulm, John D.

Atty. Docket: 2159.3210001/JMC/M-R/KMH

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

Mail Stop Amendment

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 Title 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 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 (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

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 the therapeutically effective amount of dimethyl fumarate is about 480 mg per day.
33. (new) The method of claim 32, wherein the dimethyl fumarate is administered in separate administrations of 2 equal doses.

Remarks

Upon entry of the forgoing amendment, Applicant has amended the title to correspond more clearly with the claimed subject matter. Support for this amendment is found throughout the specification as originally filed. No new matter has been added.

Claims 18-33 are pending in the application, with claims 18, 28, and 32 being the independent claims. Claims 1-17 have been cancelled without prejudice or disclaimer thereof. Support for new claims 18, 28, and 32 is found, *inter alia*, in the specification at page 6, paragraph [0017]; at page 13, paragraph [0063]; at page 25, paragraph [0104]; at pages 29-30, paragraph [0116]; and at page 30, paragraphs [0118] and [0119]. Support for new claim 19 is found, *inter alia*, in the specification at page 30, paragraph [0119]. Support for new claims 20-22, 26, 29-31, and 33 is found, *inter alia*, in the specification at pages 29-30, paragraph [0116]. Support for new claims 23 and 24 is found, *inter alia*, in the specification at page 30, paragraph [0118]. Support for new claims 25 and 27 is found, *inter alia*, in the specification at pages 13-14, paragraph [0064].

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Claims 18-27, 32, and 33 are not limited to subjects exhibiting only symptoms of multiple sclerosis. Instead, claims 18-27, 32, and 33 encompass subjects that may be undergoing treatment for other diseases and/or disorders (*e.g.*, depression). Additionally, claims 18-27, 32, and 33 encompass subjects receiving other treatments for multiple sclerosis, as well as treatments for other diseases and/or disorders (*e.g.*, depression).

Claims 28-31 are not limited to subjects exhibiting only symptoms of multiple sclerosis, nor are they limited to the route of administration. For example, claims 28-31 encompass administration of an oral composition containing one or more acceptable

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.