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:	Confirmation No.: 5998
LUKASHEV *et al.*	Art Unit: 1649
Appl. No.: 13/372,426	Examiner: ULM, John D.
Filed: February 13, 2012	Atty. Docket: 2159.3210002/JMC/MRG/U-S
For: **Treatment for Multiple Sclerosis**	

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

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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.

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.

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.

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