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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/372,426	02/13/2012	Matvey E. LUKASHEV	2159.3210002/JMC/MRG/U-S	5998

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EXAMINER	
ULM, JOHN D	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
10/12/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	13/372,426	LUKASHEV ET AL.	
	Examiner	Art Unit	
	JOHN ULM	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *18-37* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *18-37* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

DETAILED ACTION

1) Claims 18 to 37 are pending in the instant application. Claim 37 has been added as requested by Applicant in the amendment filed 03 August of 2012.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

4) Claims 18 to 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Joshi et al. patent publication (US 2003/0018072 A1) for those reasons of record as applied to claims 1 to 36 in section 4 of the office action mailed 03 May of 2012. As stated therein, these claims are drawn to a method of treating multiple sclerosis (MS) in an individual suffering therefrom by the daily oral administration thereto of dimethyl fumarate or diethyl fumarate at a rate of 480 mg per day, which is *prima facie* obvious in view of the Joshi et al. patent publication because Joshi et al. fairly taught the treatment of MS by the administration to an individual suffering therefrom an effective amount of dimethyl fumarate, methyl ethyl fumarate and diethyl fumarate. Whereas Joshi et al. does not anticipate the instant claims because it did not disclose the specific treatment protocol recited therein, one of ordinary skill in the art would have found it *prima facie* obvious to have engaged in that routine experimentation needed to determine the optimal effective protocol for such treatment.

Applicant has extensively traversed this rejection essentially on the premise that the claimed method produces particularly advantageous and unexpected results as applied to individuals suffering from multiple sclerosis (MS). The unexpected and advantageous results demonstrated for the claimed method relative to the other embodiments that are disclosed in the instant specification are not in dispute. However, neither those unexpected and allegedly advantageous results ***nor the particular combination now claimed*** are described in the specification as filed. In fact, the demonstration that the now claimed combination is operable in not unexpected. It is Applicant's discovery, subsequent to the filing of the instant application, that the majority of embodiments described in the specification are inoperative that is unexpected. The fact that dimethyl fumarate, methyl ethyl fumarate and diethyl fumarate can be successfully employed to treat MS was not unexpected as of the filing date of the instant application. The only aspect of the claimed invention that is absent from the prior art is daily dosage, and the instant specification, as filed, disclosed no particular advantage to the dosage of fumarate derivative recited in the instant claims.

The instant specification teaches the treatment of a plurality of neurological diseases including those listed in paragraphs [0104] to [0106] therein, which states that "neurological diseases suitable for the methods described herein include neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS), Parkinson's disease, Alzheimer's disease, and Huntington's disease", "MS", "acute haemorrhagic leucoencephalomyelitis, Hurst's disease, acute disseminated encephalomyelitis, optic neuritis, Devic's disease, spinal cord lesions, acute necrotizing myelitis, transverse

myelitis, chronic progressive myelopathy, progressive multifocal leukoencephalopathy (PML), radiation myelopathy, HTLV-1 associated myelopathy, monophasic isolated demyelination, central pontine myelinolysis, and leucodystrophy (e.g., adrenoleucodystrophy, metachromatic leucodystrophy, Krabbe's disease, Canavan's disease, Alexander's disease, Pelizaeus-Merbacher disease, vanishing white matter disease, oculodentodigital syndrome, Zellweger's syndrome), chronic inflammatory demyelinating polyneuropathy (CIDP), acute inflammatory demyelinating polyneuropathy (AIDP), Leber's optic atrophy," "Charcot-Marie-Tooth disease", "polyneuritis and mitochondrial disorders with demyelination". Nowhere does the instant specification, as filed, disclose a particular advantage to applying the method described therein to MS.

In addition, with respect to dimethyl fumarate (DMF) or monomethyl fumarate (MMF), the text in paragraph [0116] of the specification taught that "an effective amount can range from 1 mg/kg to 50 mg/kg (e.g., from 2.5 mg/kg to 20 mg/kg or from 2.5 mg/kg to 15 mg/kg)" and that "an effective dose of DMF or MMF to be administered to a subject orally can be from about 0.1 g to 1 g per day, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or from about 480 mg to about 720 mg per day; or about 720 mg per day)". Again, the specification, as filed, fails to demonstrate, or even predict, any particular advantage to be realized from the administration of a dosage of 480 mg per day of DMF or methyl ethyl fumarate (MEF) to an individual suffering from MS. Applicant's subsequent discovery that the vast majority of dosages described in the specification are inoperative is the only unexpected result

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