US010391160B2

(12) **United States Patent**
Viglietta

(10) **Patent No.: US 10,391,160 B2**
(45) **Date of Patent: Aug. 27, 2019**

(54) **DIMETHYL FUMARATE AND VACCINATION REGIMENS**

(71) Applicant: **Biogen MA Inc.**, Cambridge, MA (US)

(72) Inventor: **Vissia Viglietta**, Boston, MA (US)

(73) Assignee: **Biogen MA Inc.**, Cambridge, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/125,612**

(22) PCT Filed: **Mar. 13, 2015**

(86) PCT No.: **PCT/US2015/020470**

§ 371 (c)(1),
(2) Date: **Sep. 13, 2016**

(87) PCT Pub. No.: **WO2015/138917**

PCT Pub. Date: **Sep. 17, 2015**

(65) **Prior Publication Data**

US 2017/0000873 A1 Jan. 5, 2017

Related U.S. Application Data

(60) Provisional application No. 61/953,259, filed on Mar. 14, 2014.

(51) **Int. Cl.**

A61K 39/00	(2006.01)
A61K 39/05	(2006.01)
A61K 39/09	(2006.01)
A61K 31/225	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 39/092*** (2013.01); ***A61K 31/225*** (2013.01); ***A61K 39/05*** (2013.01); *A61K 2039/545* (2013.01); *A61K 2039/6081* (2013.01)

(58) **Field of Classification Search**

CPC A61K 31/225; A61K 2300/00; A61K 2039/545; A61K 2039/6081; A61K 39/05; A61K 39/092

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,509,376	B1	1/2003	Joshi et al.
9,326,947	B1	5/2016	Dyakonov et al.
9,326,965	B2	5/2016	Dyakonov et al.
9,511,043	B2	12/2016	Dyakonov et al.
9,517,209	B2	12/2016	Dyakonov et al.
9,566,259	B1	2/2017	Vaughn et al.
9,636,318	B2	5/2017	Vaughn et al.
9,636,319	B1	5/2017	Vaughn et al.
9,814,691	B2	11/2017	Dyakonov et al.
9,814,692	B2	11/2017	Vaughn et al.
9,820,960	B2	11/2017	Dyakonov et al.
9,820,961	B2	11/2017	Vaughn et al.
10,098,863	B2	10/2018	Vaughn et al.
2013/0216615	A1	8/2013	Goldman et al.
2018/0055804	A1	3/2018	Vaughn et al.
2018/0055806	A1	3/2018	Dyakonov et al.
2018/0278918	A1	9/2018	Peri et al.

FOREIGN PATENT DOCUMENTS

WO	WO 2016/057133 A1	4/1916
WO	WO 2016/081355 A1	5/1916
WO	WO 2017/040272 A1	3/1917
WO	WO 2017/151184 A1	9/1917
WO	WO 2006/037342 A2	4/2006
WO	WO 2015/130998 A1	9/2015
WO	WO 2015/138917 A1	9/2015

OTHER PUBLICATIONS

Auriel et al. (E. Auriel et al. / Journal of the Neurological Sciences 314 (2012) 102-103).*

Highlights of Prescribing Information for TecfideraTM (dimethyl fumarate) delayed-release capsules, for oral use; revised Mar. 2013.

International Preliminary Report on Patentability for International Patent Application No. PCT/US2015/020470, International Bureau of WIPO, Switzerland, dated Sep. 22, 2016.

International Search Report of International Application PCT/US2015/020470, dated Jun. 3, 2015.

Mrowietz et al., 1999, "Treatment of Severe Psoriasis with Fumaric Acid Esters: Scientific Background and Guidelines for Therapeutic Use," Br. J. Dermatol., 141(3):424-29.

Olberg et al., 2014, "Immunotherapies Influence the Influenza Vaccination Response in Multiple Sclerosis Patients: An Explorative Study," Mult. Scler., 20(8):1074-80.

Polman et al., 2010, "Diagnostic Criteria for Multiple Sclerosis: 2010 Revisions to the McDonald Criteria," Ann. Neurol., 69(2):292-02.

Schwid et al., 2005, "Enhanced Benefit of Increasing Interferon Beta-1a Dose and Frequency in Relapsing Multiple Sclerosis: The EVIDENCE Study," Arch. Neurol., 62(5):785-92.

Tecfidera—Product Information, including Annex I-III, dated Feb. 26, 2014; European Medicines Agency.

"Vaccination Response in Tecfidera-Treated Versus Interferon-Treated Participants with Relapsing Forms of Multiple Sclerosis," dated Mar. 25, 2014, ClinicalTrials.gov; [on-line], [retrieved on May 15, 2015], Retrieved from the Internet: <URL:https://www.clinicaltrials.gov/ct2/show/study/NCT02097849>.

Written Opinion of the International Searching Authority for International Application PCT/US2015/020470, dated Jun. 3, 2015.

(Continued)

Primary Examiner — Snigdha Maewall

(74) *Attorney, Agent, or Firm* — Jones Day

(57) **ABSTRACT**

Provided herein is a method of treating or preventing a disease or disorder (e.g., MS) in a subject in need thereof, comprising (a) administering to the subject a first dose of a pharmaceutical composition comprising a fumarate agent (e.g., DMF) for a first dosing period; (b) administering a vaccine; and (c) administering to the subject a second dose of the pharmaceutical composition for a second dosing period.

23 Claims, No Drawings