



US010994003B2

(12) **United States Patent**  
**Viglietta**(10) **Patent No.: US 10,994,003 B2**(45) **Date of Patent: \*May 4, 2021**(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.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/729,710**(22) Filed: **Dec. 30, 2019**(65) **Prior Publication Data**

US 2020/0360501 A1 Nov. 19, 2020

**Related U.S. Application Data**

(63) Continuation of application No. 16/391,583, filed on Apr. 23, 2019, now Pat. No. 10,555,993, which is a continuation of application No. 15/125,612, filed as application No. PCT/US2015/020470 on Mar. 13, 2015, now Pat. No. 10,391,160.

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

(51) **Int. Cl.****A61K 39/09** (2006.01)**A61K 39/05** (2006.01)**A61K 31/225** (2006.01)**A61K 39/00** (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 39/092**; **A61K 39/05**; **A61K 31/225**; **A61K 2039/545**; **A61K 2039/6081**; **A61P 37/04**; **A61P 31/00**; **A61P 25/28**

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.  
 10,391,160 B2 8/2019 Viglietta

10,555,993 B2 2/2020 Viglietta  
 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 2006/037342 A2 4/2006  
 WO WO 2015/130998 A1 9/2015  
 WO WO 2015/138917 A1 9/2015  
 WO WO 2016/081355 A1 5/2016  
 WO WO 2017/040272 A1 3/2017  
 WO WO 2017/151184 A1 9/2017

## OTHER PUBLICATIONS

Appeal Brief under 37 C.F.R. § 41.37 filed Jan. 23, 2020 for U.S. Appl. No. 16/043,641; 21 pages.  
 Appellant's Reply Brief filed May 18, 2020 for U.S. Appl. No. 16/043,641; 11 pages.  
 Applicant-Initiated Interview Summary dated Jul. 21, 2020 for U.S. Appl. No. 15/647,016; 10 pages.  
 Cahill et al., 2010, "Immunization in Patients With Multiple Sclerosis", *Neurol. Bull.* 2: 17-21.  
 Decision on Petition dated Jul. 8, 2020 for U.S. Appl. No. 16/043,641; 2 pages.  
 Declaration Under 37 C.F.R. § 1.132 of Mark Novas filed Mar. 25, 2020 for U.S. Appl. No. 16/173,723; 9 pages.  
 Declaration Under 37 C.F.R. § 1.132 of Mark Novas filed Jul. 20, 2020 for U.S. Appl. No. 15/647,016; 25 pages.  
 Examiner's Answer dated Mar. 18, 2020 for U.S. Appl. No. 16/043,641; 12 pages.  
 Extended European Search Report dated Apr. 9, 2020 for EP Application No. 19199534.9; 7 pages.  
 Notice of Non-Compliant Appeal Brief dated Feb. 3, 2020 for U.S. Appl. No. 16/043,641; 2 pages.  
 Office Action dated Jan. 23, 2020 for U.S. Appl. No. 15/527,252; 18 pages.  
 Office Action dated Jun. 10, 2020 for U.S. Appl. No. 16/173,723; 12 pages.  
 Office Action dated Jun. 24, 2020 for U.S. Appl. No. 15/647,016; 18 pages.  
 Response to Final Office Action filed Mar. 25, 2020 for U.S. Appl. No. 16/173,723; 14 pages.  
 Response to Final Office Action filed Jul. 20, 2020 for U.S. Appl. No. 15/647,016; 13 pages.  
 Response to Notice of Non-Compliant Appeal Brief filed Feb. 3, 2020 for U.S. Appl. No. 16/043,641; 6 pages.  
 Abu-Shakra, 2009, "Safety of vaccination of patients with systemic lupus erythematosus", *Lupus*, 18:1205-1208.

(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.

**26 Claims, No Drawings**