(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 October 2013 (03.10.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/148690 A1

(51) International Patent Classification:
A61K 31/4704 (2006.01)

(21) International Application Number:
PCT/US2013/033885

(22) International Filing Date:
26 March 2013 (26.03.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/616,337 27 March 2012 (27.03.2012) US
13/800,047 13 March 2013 (13.03.2013) US

(71) Applicant *(for all designated States except BB, US)*: **TEVA PHARMACEUTICAL INDUSTRIES LTD.** [IL/IL]; 5 Basel Street, P.O. Box 3190, 49131 Petach, Tikva (IL).

(71) Applicant *(for BB only)*: **TEVA PHARMACEUTICALS USA, INC.** [US/US]; 1090 Horsham Road, North Wales, PA 19454 (US).

(72) Inventor; and
(71) Applicant *(for US only)*: **FLAXMAN, Kaye, Joel** [IL/IL]; 14/5 Hazamir St., 42752 Netanya (IL).

(74) Agent: **WHITE, John, P.**; Cooper & Dunham LLP, 30 Rockefeller Plaza, New York, NY 10112 (US).

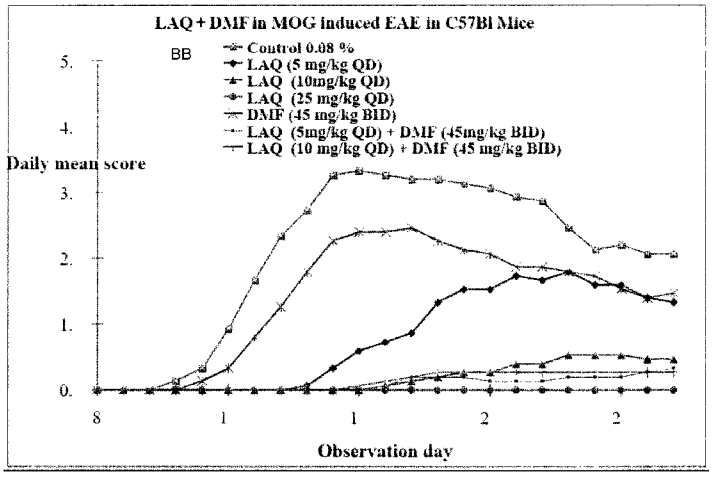
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title**: TREATMENT OF MULTIPLE SCLEROSIS WITH COMBINATION OF LAQUINIMOD AND DIMETHYL FUMARATE

Figure 1 of 1



(57) **Abstract**: This invention provides a method of treating a subject afflicted with multiple sclerosis or presenting a clinically isolated syndrome comprising administering to the subject laquinimod as an add-on therapy to or in combination with DMF. This invention also provides a package comprising laquinimod and DMF for treating a subject afflicted with multiple sclerosis or presenting a clinically isolated syndrome. This invention also provides laquinimod for use as an add-on therapy or in combination with DMF in treating a subject afflicted with multiple sclerosis or presenting a clinically isolated syndrome. This invention also provides a pharmaceutical composition comprising laquinimod and DMF for use in treating a subject afflicted with multiple sclerosis or presenting a clinically isolated syndrome. This invention further provides use of laquinimod and DMF in the preparation of a combination for treating a subject afflicted with multiple sclerosis or presenting a clinically isolated syndrome.

WO 2013/148690 A1