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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 June 2012 (28.06.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/088033 A2

(51) **International Patent Classification**:
A61K 9/28 (2006.01) *A61K 31/519* (2006.01)
A61K 9/20 (2006.01) *A61P 35/00* (2006.01)

(21) **International Application Number**:
PCT/US2011/066021

(22) **International Filing Date**:
20 December 2011 (20.12.2011)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/424,967 20 December 2010 (20.12.2010) US

(71) **Applicant** *(for all designated States except US)*: **GLAXOSMITHKLINE LLC** [US/US]; One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102 (US).

(72) **Inventors; and**
(75) **Inventors/Applicants** *(for US only)*: **DeMARINI, Douglas, J.** [US/US]; 1250 South Collegeville Road, Collegeville, PA 19426 (US). **LE, Ngocdiep, T.** [US/US]; 1250 South Collegeville Road, Collegevill, PA 19426 (US). **HENRIQUEZ, Francisco** [US/US]; 1250 South Collegeville Road, Collegeville, PA 19426 (US). **WANG, Lihong** [CA/US]; 1250 South Collegevill Road, Collegevill, PA 19426 (US).

(74) **Agents**: **DUSTMAN, Wayne, J.** et al.; Glaxosmithkline, Corporate Intellectual Property, UW2220, 709 Swedeland Road. P.O.Box 1539, King Of Prussia, PA 19406-0939 (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, 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, 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, MD, 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).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2012/088033 A2

(54) **Title**: NOVEL PHARMACEUTICAL COMPOSITION

(57) **Abstract**: Disclosed are novel pharmaceutical compositions containing N-{3-[3- cyclopropyl-5-(2-fluoro-4-iodo-phenylamino)-6,8-dimethyl-2,4,7-trioxo-3,4,6,7- tetrahydro-2H-pyrido[4,3-d]pyrimidin-1-yl]phenyl}acetamide dimethyl sulfoxide solvate, methods of using the compositions in therapy and processes for preparing the same.