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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 April 2010 (01.04.2010)

PCT

(10) International Publication Number
WO 2010/036686 A1

(51) **International Patent Classification**:
A61K 9/20 (2006.01) ***A61K 31/41*** (2006.01)
A61K 31/165 (2006.01)

(21) **International Application Number**:
PCT/US2009/057993

(22) **International Filing Date**:
23 September 2009 (23.09.2009)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/099,595 24 September 2008 (24.09.2008) US
61/161,799 20 March 2009 (20.03.2009) US

(71) **Applicant** *(for all designated States except US)*: **NOVARTIS AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(72) **Inventors; and**

(75) **Inventors/Applicants** *(for US only)*: **GHOSH, Indrajit** [IN/US]; 130 New Road, K-19, Parsippany, New Jersey 07054 (US). **KOWALSKI, James** [US/US]; 38 Summit Road, Belle Mead, New Jersey 08502 (US). **SNYDER, Jennifer** [US/US]; 16 Brook Drive North, Morris Plains, New Jersey 07950 (US). **TONG, Wei-Qin** [US/US]; 1 Wellington Drive, Basking Ridge, New Jersey 07920 (US). **VIPPAGUNTA, Sudha** [IN/US]; 194 Patriots Road, Morris Plains, New Jersey 07950 (US).

(74) **Agent**: **MATOVCIK, Lisa**; Novartis, Patent Department, One Health Plaza, Bldg. 101, East Hanover, New Jersey 07936 (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, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, 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))*

WO 2010/036686 A1

(54) **Title**: GALENICAL FORMULATION COMPRISING ALISKIREN AND PROCESS FOR ITS PREPARATION BY MELT EXTRUSION GRANULATION

(57) **Abstract**: The present invention relates to galenic formulations wherein the active ingredient aliskiren, preferably, a hemi-fumarate salt thereof, alone or in combination with another active ingredient, is melt-granulated and is present in an amount of more than 20% by weight based on the total weight of the oral dosage form, as well as a process of preparing said solid oral dosage form.