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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 September 2009 (24.09.2009)

PCT

(10) International Publication Number
WO 2009/117277 A2

(51) International Patent Classification:
A61K 31/337 (2006.01) *A61K 31/517* (2006.01)
A61K 31/416 (2006.01) *A61K 31/5355* (2006.01)
A61K 31/513 (2006.01) *A61K 31/555* (2006.01)

(21) International Application Number:
PCT/US2009/036608

(22) International Filing Date:
10 March 2009 (10.03.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/037,410 18 March 2008 (18.03.2008) US

(71) Applicant *(for all designated States except US)*: **GENENTECH, INC.** [US/US]; 1 DNA Way, South San Francisco, CA 94080 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BERRY, Leanne** [US/US]; 216 Myrtle Road, Apt. 3, Burlingame, CA 94010 (US). **PHILLIPS, Gail, Lewis** [US/US]; 515 De Anza Avenue, San Carlos, CA 94070 (US). **SLIWKOWSKI, Mark, X.** [US/US]; 42 Oak Creek Lane, San Carlos, CA 94070 (US).

(74) Agents: **ANDRUS, Alex** et al.; 1 DNA Way, MS 49, South San Francisco, CA 94080 (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, 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, 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, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

WO 2009/117277 A2

(54) **Title**: COMBINATIONS OF AN ANTI-HER2 ANTIBODY-DRUG CONJUGATE AND CHEMOTHERAPEUTIC AGENTS, AND METHODS OF USE

(57) **Abstract**: Combinations of the antibody-drug conjugate trastuzumab-MCC-DM1 and chemotherapeutic agents, including stereoisomers, geometric isomers, tautomers, solvates, metabolites and pharmaceutically acceptable salts thereof, are useful for inhibiting tumor cell growth, and for treating disorders such as cancer mediated by HER2 and KDR (VEGFR receptor 1). Methods of using such combinations for *in vitro, in situ*, and *in vivo* diagnosis, prevention or treatment of such disorders in mammalian cells, or associated pathological conditions, are disclosed.