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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 October 2010 (14.10.2010)

PCT

(10) International Publication Number
WO 2010/117633 A1

(51) International Patent Classification:
A61K 31/4709 (2006.01) *A61P 35/00* (2006.01)

(21) International Application Number:
PCT/US2010/028448

(22) International Filing Date:
24 March 2010 (24.03.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/166,796 6 April 2009 (06.04.2009) US

(71) Applicant *(for all designated States except US)*: **WYETH LLC** [US/US]; Five Giralda Farms, Madison, New Jersey 07940 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BERKENBLIT, Anna** [US/US]; 60 Hoover Road, Needham, Massachusetts 02494 (US). **BINLICH, Florence** [FR/FR]; 35 Avenue Thierry, F-92410 Ville D'Avray (FR). **GOSS, Paul** [CA/US]; 904 Washington Street, Wellesley, Massachusetts 02482 (US).

(74) Agents: **RUBIN, David, A.** et al.; Wyeth, Patent Law Department, Five Giralda Farms, Madison, New Jersey 07940 (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, 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, 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).

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))*

Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

WO 2010/117633 A1

(54) Title: TREATMENT REGIMEN UTILIZING NERATINIB FOR BREAST CANCER

(57) Abstract: An extended regimen for treatment of HER-2/neu overexpressed/amplified cancer is described, with involves delivering a course of neratinib therapy to HER-2/neu overexpressed/amplified cancer patients following the completion of surgical and adjuvant therapy. The neratinib regimen may be continued for upwards of twelve months to five years. Also provided are pharmaceutical kits designed to facilitate compliance with the regimen.