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

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 February 2005 (10.02.2005)

PCT

(10) International Publication Number
WO 2005/012527 A1

(51) International Patent Classification[7]: C12N 15/12, 15/86, 7/00, 5/10

(21) International Application Number: PCT/EP2004/008234

(22) International Filing Date: 20 July 2004 (20.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/489,237 21 July 2003 (21.07.2003) US

(71) Applicant *(for all designated States except US)*: **ISTITUTO DI RICERCHE DI BIOLOGIA MOLECOLARE P ANGELETTI SPA** [IT/IT]; Via Pontina KM 30.600, I-00040 Pomezia (Rome) (IT).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **GALLO, Pasquale** [IT/IT]; IRBM, Via Pontina KM 30.600, I-00040 Pomezia (Rome) (IT). **MONACI, Paolo** [IT/IT]; IRBM, Via Pontina KM 30.600, I-00040 Pomezia (Rome) (IT). **NUZZO, Maurizio** [IT/IT]; IRBM, Via Pontina KM 30.600, I-00040 Pomezia (Rome) (IT).

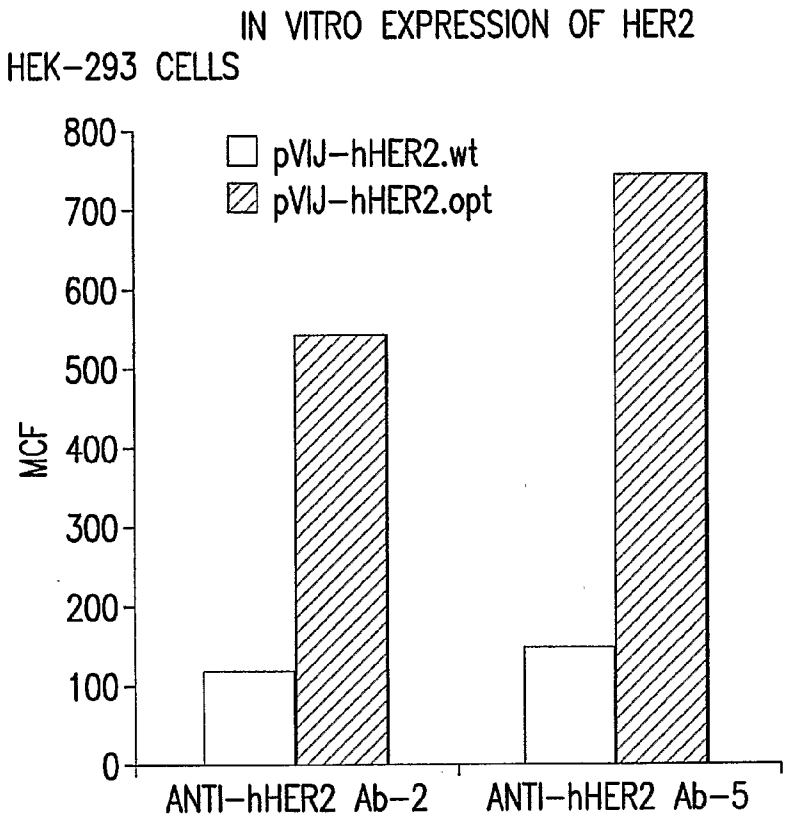
(74) Agent: **BUCHAN, Gavin, MacNicol**; Terlings Park, Eastwick Road, Harlow, Essex CM20 2QR (GB).

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

(54) Title: SYNTHETIC GENE ENCODING HUMAN EPIDERMAL GROWTH FACTOR 2/NEU ANTIGEN AND USES THEREOF



(57) Abstract: Synthetic polynucleotides encoding human HER2/neu or a truncated form thereof, are provided, the synthetic polynucleotides being codon-optimized for expression in a human cellular environment. The gene encoding hHER2 is commonly associated with the development of human carcinomas. The present invention provides compositions and methods to elicit or enhance immunity to the protein product expressed by the hHER2 tumor-associated antigen, wherein aberrant hHER2 expression is associated with a carcinoma or its development. This invention specifically provides adenoviral vector and plasmid constructs carrying codon-optimized human HER2 and codon-optimized truncated HER2, and discloses their use in vaccines and pharmaceutical compositions for preventing and treating cancer.

WO 2005/012527 A1

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, HU, IE, IT, LU, MC, NL, 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:

— *with international search report*

(48) Date of publication of this corrected version:
2 March 2006

(15) Information about Correction:
see PCT Gazette No. 09/2006 of 2 March 2006, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.