



- (51) **International Patent Classification:**
C07K 14/445 (2006.01)
- (21) **International Application Number:**
PCT/US2013/037656
- (22) **International Filing Date:**
22 April 2013 (22.04.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/641,105 1 May 2012 (01.05.2012) US
13/844,261 15 March 2013 (15.03.2013) US
- (63) **Related by continuation (CON) or continuation-in-part (CIP) to earlier application:**
US 13/844,261 (CIP)
Filed on 15 March 2013 (15.03.2013)
- (71) **Applicant:** PFENEX INC. [US/US]; 10790 Roselle Street, San Diego, CA 92121 (US).
- (72) **Inventors:** ALLEN, Jeffrey; 14702 Fairtree Terrace, Poway, CA 92064 (US). CANTIN, Greg; 429 S Sierra Ave., #137, Solana Beach, CA 92075 (US). HAVERSTOCK, Ryan; 2035 Shadytree Lane, Encinitas, CA 92024 (US).
- (74) **Agent:** CHANG, Ardith; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304 (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, BN, 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, PA, 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, 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).

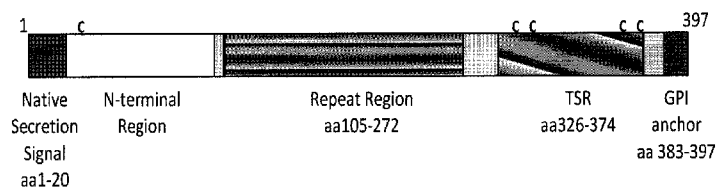
Declarations under Rule 4.17:

- 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))

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))
- with sequence listing part of description (Rule 5.2(a))

(54) **Title:** PROCESS FOR PURIFYING RECOMBINANT PLASMODIUM FALCIPARUM CIRCUMSPOROZOITE PROTEIN

FIG. 1

(57) **Abstract:** The present invention relates to processes for purifying high-quality recombinant *Plasmodium falciparum* circumsporozoite protein at high yields. This process provides rCSP at high yields without the need for denaturing and refolding the protein. The present invention overcomes obstacles previously encountered in the field, including dimerization, aggregation, and N-terminal degradation of rCSP. The process provided by the invention is scalable, and can be applied to large fermentation batches. The invention also relates to stable liquid formulations of recombinant *P. falciparum* circumsporozoite protein, and processes for stably maintaining rCSP in a stable liquid formulation.