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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 May 2011 (12.05.2011)

PCT

(10) International Publication Number
WO 2011/056590 A1

(51) International Patent Classification:
G01N 33/50 (2006.01) *G01N 33/564* (2006.01)

(21) International Application Number:
PCT/US2010/054125

(22) International Filing Date:
26 October 2010 (26.10.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/255,048	26 October 2009 (26.10.2009)	US
61/262,877	19 November 2009 (19.11.2009)	US
61/324,635	15 April 2010 (15.04.2010)	US
61/345,567	17 May 2010 (17.05.2010)	US
61/351,269	3 June 2010 (03.06.2010)	US
61/389,672	4 October 2010 (04.10.2010)	US
61/393,581	15 October 2010 (15.10.2010)	US

(71) Applicant *(for all designated States except US)*: **PROMETHEUS LABORATORIES INC.** [US/US]; 9410 Carroll Park Drive, San Diego, California 92121-5201 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SINGH, Sharat** [US/US]; 8171 Top of the Morning Way, Rancho Santa Fe, California 92127 (US). **WANG, Shui Long** [US/US]; 4555 Saddle Mountain Court, San Diego, California 92130 (US). **OHRMUND, Linda** [US/US]; 10284 Wateridge Circle #242, San Diego, California 92121 (US).

(74) Agents: **HAO, Joe C.** et al.; TOWNSEND and TOWNSEND and CREW LLP, Two Embarcadero Center, Eighth Floor, San Francisco, California 94111-3834 (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 (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).

[Continued on next page]

(54) Title: ASSAYS FOR THE DETECTION OF ANTI-TNF DRUGS AND AUTOANTIBODIES

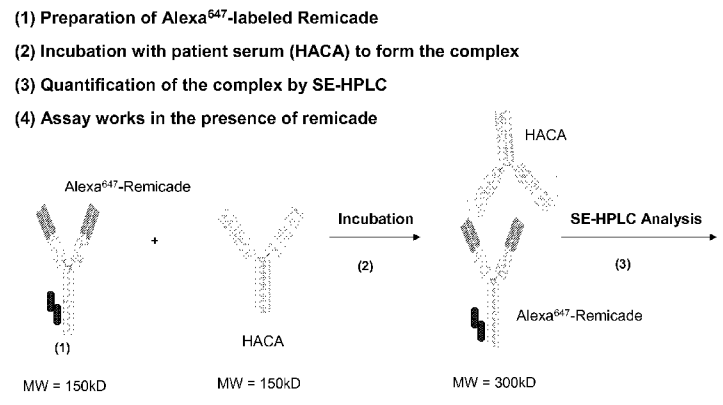


FIG. 4

(57) Abstract: The present invention provides assays for detecting and measuring the presence or level of anti-TNFα drug therapeutics and autoantibodies in a sample. The present invention is useful for optimizing therapy and monitoring patients receiving anti-TNFα drug therapeutics to detect the presence or level of autoantibodies (e.g., HACA and/or HAHA) against the drug.

WO 2011/056590 A1

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))*