



- (51) **International Patent Classification:**
G01N 33/574 (2006.01) *G01N 33/532* (2006.01)
G01N 33/68 (2006.01) *G01N 33/543* (2006.01)
- (21) **International Application Number:**
PCT/US2012/055416
- (22) **International Filing Date:**
14 September 2012 (14.09.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/534,791 14 September 2011 (14.09.2011) US
- (71) **Applicant (for all designated States except US):** UNIVERSITY OF WASHINGTON THROUGH ITS CENTER FOR COMMERCIALIZATION [US/US]; 4311 11th Avenue NE, Suite 500, Seattle, Washington 98105 (US).
- (72) **Inventor; and**
- (75) **Inventor/Applicant (for US only):** LIU, Alvin Y. [US/US]; 15178 NE 8th Place, Bellevue, Washington 98007 (US).
- (74) **Agents:** FITZGERALD, Mark J. et al.; NIXON PEABODY LLP, 100 Summer Street, Boston, Massachusetts 02110-2131 (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).

Published:
— with international search report (Art. 21(3))

[Continued on next page]

(54) **Title:** ASSAYS AND COMPOSITIONS FOR DETECTION OF AGR2

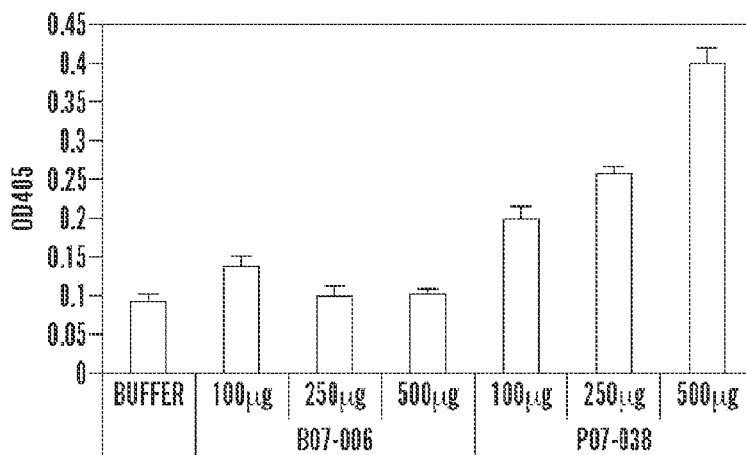


FIG. 8A

(57) **Abstract:** The technology described herein relates to the diagnosis, prognosis, and treatment of cancer, e.g. prostate cancer, according to methods and compositions for the detection of AGR2.

WO 2013/040358 A3



-
- *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))*

(88) Date of publication of the international search report:
10 May 2013

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/055416**A. CLASSIFICATION OF SUBJECT MATTER***G01N 33/574(2006.01)i, G01N 33/68(2006.01)i, G01N 33/532(2006.01)i, G01N 33/543(2006.01)i*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01N 33/574; A61K 39/395; C07K 16/18; C07C 261/00; C12Q 1/68; G01N 33/50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: Anterior gradient homolog 2, AGR2, antibody, prostate cancer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US20110052586 A1 (BARRACLOUGH, ROGER et al.) 03 March 2011 See abstract; paragraphs [0010], [0027], and [0035]-[0036]; claims 1, 7-11, and 15.	43-45
A	7429382 B2 (NISHIZUKA, TOSHIO et al.) 21 October 2008 See abstract; column 46, lines 5-6; SEQ ID NO: 26.	43-45
A	ZHANG, JIN-SAN et al. 'AGR2, an androgen-inducible secretory protein overexpressed in prostate cancer', Genes Chromosomes & Cancer, 2005, Vol.43, No.3, pp.249-259. See abstract; p.251, left column.	43-45
A	ZHANG, Y. et al. 'Increased expression of anterior gradient-2 is significantly associated with poor survival of prostate cancer patients', Prostate Cancer and Prostatic Diseases, 2007, Vol.10, No.3, pp.293-300. See abstract; p.294.	43-45
A	US20100062426 A1 (O'HARA, SHAWN MARK et al.) 11 March 2010 See abstract; paragraph [0008]; claims 1, 4, and 9.	43-45

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

25 FEBRUARY 2013 (25.02.2013)

Date of mailing of the international search report

26 FEBRUARY 2013 (26.02.2013)

Name and mailing address of the ISA/KR



Facsimile No. 82-42-472-7140

Authorized officer

HEO, Joo Hyung

Telephone No. 82-42-481-8150



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/055416

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2008067065 A2 (SRIVASTAVA, SHIV et al.) 05 June 2008 See abstract; paragraph [0018]; claims 14, 16, and 20.	43-45

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/055416**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 1-42,59
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-42 and 59 pertain to methods for treatment of the human body by therapy and diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. Claims Nos.: 53,56
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
claims 53 and 56 are unclear since it is referring to the multiple dependent claims which do not comply with PCT Rule 6.4(a).
3. Claims Nos.: 7-19, 23-30, 36-42, 46-52, 54, 55, 57-59
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/055416

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US20110052586 A1	03.03.2011	AT 474857 T	15.08.2010
		AU 2007-291077 A1	06.03.2008
		AU 2007-291077 B2	08.03.2012
		CA 2661803 A1	06.03.2008
		DE 602007007958 D1	02.09.2010
		DK 2054443 T3	15.11.2010
		EP 2054443 A2	06.05.2009
		EP 2054443 B1	21.07.2010
		ES 2351801 T3	10.02.2011
		GB 0616929 D0	04.10.2006
		PT 2054443 E	26.10.2010
		US 8329875 B2	11.12.2012
		WO 2008-025964 A2	06.03.2008
		WO 2008-025964 A3	12.06.2008
		7429382 B2	21.10.2008
AU 2003-231542 A1	02.12.2003		
CN 1653034 A	10.08.2005		
CN 1653034 C0	26.03.2008		
EP 1506954 A1	16.02.2005		
EP 1506954 A4	06.09.2006		
JP 4637573 B2	23.02.2011		
KR 10-1018978 B1	02.03.2011		
TW I338679 B	11.03.2011		
US 2005-0143454 A1	30.06.2005		
WO 03-097572 A1	27.11.2003		
US20100062426 A1	11.03.2010	WO 2007-053142 A1	10.05.2007
W02008067065 A2	05.06.2008	WO 2008-067065 A3	12.03.2009