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- (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, 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.
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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))

[Continued on next page]

(54) **Title:** SYSTEMS AND METHODS FOR ANTI-PAX8 ANTIBODIES

(57) **Abstract:** The present invention is related to the anti-PAX8 antibodies, kits, cocktails, and use of anti-PAX8 antibodies for detection of cancer.

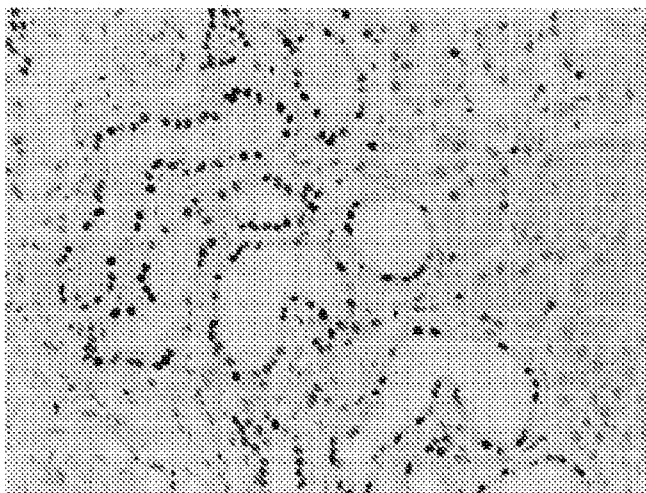


FIG. 1



— *with sequence listing part of description (Rule 5.2(a))*

(88) Date of publication of the international search report:

11 April 2013

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/37367

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 33/574, C07K 16/32 (2013.01)

USPC - 435/7.23, 530/387.7

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)

IPC(8): G01N 33/574, C07K 16/32 (2013.01)

USPC: 435/7.23, 530/387.7

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 530/387.1, 530/388.1, 530/388.8, 435/6.14

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

PubWEST, Google Scholar, PatBase: Immunohistochemistry, automated staining, ELISA, IRC, FFPE, ICR, radioactive, magnetic, radioisotope, fluorescent, enzyme, toxin, signal, stain, cancer, label, antigen, mouse, rabbit, goat, horse, chicken, humanized, chimeric, monoclonal, PAX8, antibodies, PTA-11873, hybridoma

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	WO 2012/154983 A2 (QI et al.) 15 November 2012 (15.11.2012); page 10, ln 20-24	1-4, 33-53, 63-69 and 89-90
A	US 6,723,506 B2 (FLETCHER et al.) 20 April 2004 (20.04.2004) col 37, ln 19-21	1-4, 33-53, 63-69 and 89-90
A	BOWEN et al., Emerging roles for PAX8 in ovarian cancer and endosalpingeal development. Gynecologic Oncology, Vol 104, No 2, February 2007, Pages 331-337	1-4, 33-53, 63-69 and 89-90

☐ Further documents are listed in the continuation of Box C.

* 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 another 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

24 January 2013 (24.01.2013)

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/37367

Continuation of: Box No. III Observations where unity of invention is lacking

Group IV: Claims 12-29, 32, 40-49, 63-90, drawn to a composition comprising at least two antibodies, wherein at least one antibody binds to PAX8 and method of using said composition for detecting at least two different proteins in a biological sample

Group V: Claims 30-31, 32-49, 63-69, 89-90, drawn to an antibody having a binding specificity of PAX8 and which does not bind to B Cells

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The shared technical feature of the inventions listed as Groups I-V is an antibody, and more specifically, an antibody that binds to PAX8. This shared technical feature fails to provide a contribution over the prior art, as evidenced by the article entitled "Emerging roles for PAX8 in ovarian cancer and endosalpingeal development" by Bowen et al. (published in Gynecologic Oncology, Volume 104, Issue 2, February 2007, Pages 331-337; hereinafter 'Bowen'). Bowen discloses an antibody that specifically binds to PAX8 (p 334, col 1, para 1 - "IHC using PAX8 specific antibodies incubated with BG-1 and OVCAR-3 cells revealed intense nuclear localization of PAX8 in the OVCAR-3 cell line") and use of the antibody for detecting ovarian cancer (abstract - "Immunohistochemistry, immunoblotting and RT-PCR were used to investigate the presence of PAX8 and its protein products in epithelial ovarian cancer subtypes"). In the absence of a contribution over the prior art, the shared technical feature is not a shared special technical feature.

Further, the special technical feature of the inventions listed as Group I is hybridoma cell is deposited at the American Type Culture Collection (ATCC) under ATCC Patent Deposit Designation No. PTA-11873. This special technical feature is not shared by the inventions of Groups II-V. The special technical feature of the inventions listed as Group II is an antibody comprising SEQ ID NOs: 1 or 2. This special technical feature is not shared by the inventions of Groups I and III-V. The special technical feature of the inventions listed as Group III is a peptide comprising SEQ ID NO:3. This special technical feature is not shared by the inventions of Groups I-II and IV-V. The special technical feature of the inventions listed as Group IV is a composition comprising at least two antibodies. This special technical feature is not shared by the inventions of Groups I-III and V. The special technical feature of the inventions listed as Group V is an antibody that does not bind to B cells. This special technical feature is not shared by the inventions of Groups I-IV.

Therefore, the inventions of Groups I-V lack unity with one another because they fail to share the same or corresponding special technical feature.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/37367

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing filed or furnished:

a. (means)

☐

on paper

☒

in electronic form

b. (time)

☐

in the international application as filed

☒

together with the international application in electronic form

☐

subsequently to this Authority for the purposes of search

2. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/37367

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.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
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:
3. ☒ Claims Nos.: 54-62
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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-4, 33-53, 63-69, 89-90, drawn to a hybridoma cell or antibody produced by the hybridoma, wherein the hybridoma cell is deposited at the American Type Culture Collection (ATCC) under ATCC Patent Deposit Designation No. PTA-11873

Group II: Claims 5-10, 32, 37-53, 63-69, 89-90, drawn to an antibody comprising a polypeptide encoded by the nucleic acid sequence of SEQ ID NO:1 or SEQ ID NO:2

Group III: Claims 11, 32-36, 40-53, 63-69, 89-90, drawn to an antibody that binds to a polypeptide comprising SEQ ID NO:3

---please see continuation on extra sheet---

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 additional fees, this Authority did not invite payment of additional fees.
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.:
1-4, 33-53, 63-69, 89-90

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.