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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))

(54) Title: METHOD OF IDENTIFYING TUMOR SPECIFIC MACROMOLECULAR ISOFORMS

(57) Abstract: The present disclosure provides methods for the identification of tumor-specific isoforms of polymorphic gene expression products. Methods of using said isoforms in the diagnosis and/or treatment of cancers and neoplasias are also provided.



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INTERNATIONAL SEARCH REPORT

International application No.

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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.: 4-7, 12-14, 18-27
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 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.:

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

International application No.

PCT/US2019/017013

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - C07K 16/00; C12Q 1/02; C12Q 1/68; C12Q 1/6886; G01N 33/574; G01N 33/68 (2019.01)
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 C12Q 2600/16; G01N 33/574; G01N 33/57415; G01N 2333/4713; G01N 2333/4716; G01N
 2333/4724; G01N 2333/775; G01N 2333/79; G01N 2333/8125 (2019.02)

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)

See Search History document

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

USPC - 424/133.1; 435/29; 435/6.12; 436/64; 436/71; 436/86 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/0342504 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 30 November 2017 (30.11.2017) entire document	1-3, 8-11, 15-17
A	✓ BARRETT et al. "Systematic Transcriptome Analysis Reveals Tumor-Specific Isoforms for Ovarian Cancer Diagnosis and Therapy," Proc. Natl. Acad. Sci. U.S.A., 09 June 2015 (09.06.2015), Vol. 112, No. 23, Pgs. 3050-3057. entire document	1-3, 8-11, 15-17
A	✓ CAPPER et al. "Assessment of BRAF V600E Mutation Status by Immunohistochemistry with a Mutation-Specific Monoclonal Antibody," Acta Neuropathologica, 01 July 2011 (01.07.2011), Vol. 122, No. 1, Pgs. 11-9. entire document	1-3, 8-11, 15-17
A	US 2010/0129846 A1 (GOLDKNOPF) 27 May 2010 (27.05.2010) entire document	1-3, 8-11, 15-17
A	✓ TANG et al. "Protein Isoform-Specific Validation Defines Multiple Chloride Intracellular Channel and Tropomyosin Isoforms as Serological Biomarkers of Ovarian Cancer," J Proteomics, 26 August 2013 (26.08.2013), Vol. 89, Pgs. 165-178. entire document	1-3, 8-11, 15-17
A	US 2014/0302059 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 09 October 2014 (09.10.2014) entire document	1-3, 8-11, 15-17
A	US 2015/0017159 A1 (VIB VZW et al) 15 January 2015 (15.01.2015) entire document	1-3, 8-11, 15-17
A	✓ ZHANG et al. "Profiling Alternatively Spliced mRNA Isoforms for Prostate Cancer Classification," BMC Bioinformatics, 11 April 2006 (11.04.2006), Vol. 7, Pgs. 1-12. entire document	1-3, 8-11, 15-17

☐ 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 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

26 March 2019

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