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11 September 2009

(54) Title: BIOMARKERS FOR THE DIAGNOSIS AND TREATMENT OF PANCREATIC CANCER

(57) Abstract: Compositions and methods which indicate an increased risk for pancreatic carcinoma are disclosed.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/31587

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - C12Q 1/68; G01N 33/50 (2009.01)

USPC - 435/6; 702/19

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)
USPC- 435/6; 702/19

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

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

Dialog Classic Web (344,347-349,371,652,654,345,351), Google: Biomarkers, diagnosis, pancreatic cancer, carcinoma, tumor, human, malignant, cyst fluid, mucin 1, mucin 2, mucin 5AC, mucin 5B, mucin 6, CEA CAM 1, CEACAM 5 (or CEA), CEACAM 6, CEACAM 7, CEACAM 8, S100-A6, S100-A8, S100 A9 and S100 A-11, Mucin

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2002/0150894 A1 (Batra, et al.) 17 Oct 2002 (17.10.2002) (abstract; claim 13; para [0023], [0067], [0011], [0015], [0018], [0111], [0109], [0036], [0065]).	1-2, 7 ----- 5-6
Y	Wang, et al. Diagnostic value of mucins (MUC1, MUC2 and MUC5AC) expression profile in endoscopic ultrasound-guided fine-needle aspiration specimens of the pancreas. Int. J. Cancer 2007, 121:2716-2722; abstract, Table VI	5-6
A	US 2007/0140966 A1 (Chang, et al.) 21 Jun 2007 (21.06.2007) (para [0027], [0032])	9-11
A	US 2007/0231822 A1 (Mitas, et al.) 04 Oct 2007 (04.10.2007) abstract	9-11
A	Gesierich, et al. Colocalization of the Tetraspanins, CO-029 and CD151, with Integrins in Human Pancreatic Adenocarcinoma: Impact on Cell Motility. Clin Cancer Res 2005; 11(8):2840-2852; abstract	9-11

☐ 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

28 May 2009 (28.05.2009)

Date of mailing of the international search report

25 JUN 2009

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/31587

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.:
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:

Group I, claims 1, 2, 5-7, drawn to a method comprising analyzing a pancreatic cyst fluid specimen for the presence of at least three biomarkers, wherein said biomarkers are mucin 1, mucin 2, mucin 5AC. [Note: Group I is limited to claims 1, 2, 5-7, drawn to a method comprising analyzing a pancreatic cyst fluid specimen for the presence of at least three biomarkers, wherein said biomarkers are mucin 1, mucin 2, mucin 5AC, NOT to claims 1, 2, 4-7, as was stated in the original 206.]

Group II, claims 1, 3-7, drawn to a method comprising analyzing a pancreatic cyst fluid specimen for the presence of at least three biomarkers, wherein said biomarkers are at least two mucins and at least two CEACAMs.

Group III, claims 1, 5-8, drawn to a method comprising analyzing a pancreatic cyst fluid specimen for the presence of three biomarkers, wherein said biomarkers are Mucin 5B, CEACAM5 and CEACAM 6.

--continued in supplemental box--

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.:

Group I and Group 4+, limited to at least 5 biomarkers of claim 11.
Claims 1-7, 9-11, limited to mucine 1, mucin 2, mucin 5A and biomarkers of claim 11.
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/US 09/31587

***** SUPPLEMENTAL BOX *****

Continuation of Box III Observations where unity of invention is lacking:

Group IV+, claims 1-7, 9-11 drawn to a method comprising analyzing a pancreatic cyst fluid specimen for the presence of three biomarkers. Should additional fee be paid, Applicant is invited to elect additional combination of biomarkers to be searched. The exact claims searched will depend on the specifically elected small molecule.

The inventions listed as Groups I-IV+ 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:

Groups I-IV+ do share the technical feature of analyzing a specimen for the presence of at least three markers. However, this shared technical feature does not represent a contribution over the prior art of US 2005/0100903 A1 (Neumaier), which teaches a diagnostic method for the recognition of tumor precursor cells (claim 42), comprising the step of determination of the expression of CEACAM-1, CEACAM-6, CEACAM-7 and/or CEA (claim 44). Thus, the shared technical feature cannot be considered a special technical feature that would otherwise unify the groups.

Groups I-IV+ therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.