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(54) Title: METHODS, COMPOSITIONS, AND KITS FOR THE DETECTION AND MONITORING OF COLON CANCER

(57) Abstract: Methods and compositions for the diagnosis and monitoring of colon cancer are disclosed.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/019529

A. CLASSIFICATION OF SUBJECT MATTER
INV. C12Q1/68

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)
C12Q

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 practical, search terms used)
EPO-Internal, Sequence Search, WPI Data, BIOSIS, EMBASE

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/12328 A (CORIXA CORP [US]; KING GORDON E [US]; MEAGHER MADELEINE JOY [US]; XU J) 14 February 2002 (2002-02-14) abstract, p. 47, l. 1, 2, p. 48, l. 8-28, p. 62, l. 21-27, and claims 1, 6, 8, 11, 14-16	4, 5, 9, 10, 13-28
X	WO 98/53319 A (UNIV JOHNS HOPKINS [US]; VOGELSTEIN BERT [US]; KINZLER KENNETH W [US]) 26 November 1998 (1998-11-26) abstract, p. 12, l. 26-29 to p. 13, l. 5, tab. 1 and 2, claim 1 and p. 82-83	4, 5, 9, 10, 13-28
X	WO 01/55163 A (HUMAN GENOME SCIENCES INC [US]; ROSEN CRAIG A [US]; BARASH STEVEN C [U]) 2 August 2001 (2001-08-02) [12], [446]-[452]	1, 6, 11, 12, 17-22

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

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| <p>* Special categories of cited documents :</p> <ul style="list-style-type: none"> *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document 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 | <ul style="list-style-type: none"> *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. *Z* document member of the same patent family |
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Date of the actual completion of the international search <p align="center">18 July 2008</p>	Date of mailing of the international search report <p align="center">31/10/2008</p>
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer <p align="center">Berillon-Lapopin, L</p>
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/019529

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.: 2, 3, 7, 8
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

see additional 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 an 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, 4-6 and 9-28 (partly)

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 2,3,7,8

1. The present claims 2, 3, 7, and 8 relate to a composition, a diagnostic kit and an array comprising at least one or two primers specific for any of the polynucleotides recited in SEQ ID Nos 1-17, 19-21 and 218-220, respectively. However, there is no indication either in the said claims or in the description with respect to the sequence and length that these primers should have. This would require an equally unquantifiable and thus unreasonable amount of experimentation, imposing a severe and undue burden on all those wishing to test the design all possible primers in order to ascertain the scope of the claim, which is not in compliance with the clarity requirement of Article 6 PCT. The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCTGuidelines, 9.19 and 9.24).

As a consequence, claims 2, 3, 7 and 8 are not searched whereas the extent of the search for claims 6 and 11 is limited to the clearly defined features, i.e. to a diagnostic kit and an array comprising probes specific to the SEQ ID Nos as recited in the respective claims.

2. Moreover, claims 2, 3, 7 and 8 relate to at least two primers specific for any of the polynucleotides recited in SEQ ID Nos 1-17, 19-21 and 218-220. Thus said claims relate to a high number of primer combinations. However, support and disclosure in the sense of Art. 5 and 6 PCT is lacking for any primer combination specific for the marker sequences as recited in said respective claims. The description merely discloses a list of marker sequences which are individually differentially expressed in colon cancer. Therefore, no meaningful search could be carried out for claims 2, 3, 7 and 8.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 4-6, and 9-28 (partly)

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes or peptide sequences/antibodies specific for sequences derived from the colon cancer-associated marker C1085C i.e. SEQ ID Nos. 1, 7-17 (polynucleotide sequences) and 18 (polypeptide sequence) (see description p. 10-25 and p. 73-80) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated marker C1085C.

2. claims: claims 1, 11, 12, 17-28 (partly)

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes specific for sequences derived from the colon cancer-associated markers C1086C, i.e. SEQ ID Nos. 2 (see description p. 10-25) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated markers C1086C.

3. claims: 1, 11, 12, 17-28 (partly)

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes specific for sequences derived from the colon cancer-associated markers C1087C, i.e. SEQ ID Nos. 3 (see description p. 10-25) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated markers C1087C.

4. claims: 1, 11, 12, 17-28 (partly)

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes specific for sequences derived from the colon cancer-associated markers C1088C, i.e. SEQ ID Nos. 4 (see description p. 10-25) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated markers C1088C.

5. claims: 1, 11, 12, 17-28 (partly)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes specific for sequences derived from the colon cancer-associated markers C1089C, i.e. SEQ ID Nos. 5 (see description p. 10-25) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated markers C1089C.

6. claims: claims 1, 4-6, 9-28 (partly)

concern a composition, a diagnostic kit and an array comprising oligonucleotide sequences/probes or peptide sequences/antibodies specific for sequences derived from the colon cancer-associated marker C1097C i.e. SEQ ID Nos. 6, 19-100, 218-221 (see description p. 10-25 and p. 73-80) and a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated marker C1097C.

7. claims: invention 7: claims 17-28 (partly)

concern a method for detecting the presence of colon cancer cells based on monitoring the expression level the colon cancer-associated marker C1057C.

8. claims: invention 8: claims 4, 5, 9, 10, 13-16 (partly)

concern a composition, a diagnostic kit and an array comprising peptide sequences/antibodies specific for sequences derived from the SEQ ID Nos. 101-217 (see description p. 10-25).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/019529

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