

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 October 2009 (01.10.2009)

PCT

(10) International Publication Number
WO 2009/120802 A3

- (51) **International Patent Classification:**
C12Q 1/68 (2006.01) *C12N 15/11* (2006.01)
- (21) **International Application Number:**
PCT/US2009/038288
- (22) **International Filing Date:**
25 March 2009 (25.03.2009)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/039,410 25 March 2008 (25.03.2008) US
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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, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, 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))
- 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))

- (88) **Date of publication of the international search report:**
15 April 2010

(54) **Title:** METHODS AND COMPOSITIONS FOR IDENTIFYING BIOMARKERS USEFUL IN CHARACTERIZING BIOLOGICAL STATES

(57) **Abstract:** The present invention relates to methods, compositions, and kits for identifying biomarkers useful in characterizing biological states. In particular, the invention relates to methods and compositions for molecular characterization of biological states by gene expression profiling. The invention also relates to assessing effects of DNA polymorphisms on regulation of transcription. The biomarkers and polymorphisms identified find use in diagnostic and treatment approaches, e.g., some embodiments of the invention provide methods and kits for detecting bronchogenic carcinoma and risks thereof.



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/038288**A. CLASSIFICATION OF SUBJECT MATTER***C12Q 1/68(2006.01)i, C12N 15/11(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)

C12Q 1/68; C07H 21/04; C12P 19/34; G01N; NotA vai/lable

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

(Chinese Patents and application for patent)

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

eKOMPASS(KIPO internal), NCBI database, google, google scholar

& Keywords: transcription, gene expression, compatitive amplification, polymorphism, label

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5639606 A1 (WILLEY; JAMES C.) 17 June 1997 See abstract and claims.	1-8 9-21
X A	WO 2005-086679 A2 (MEDICAL COLLEGE OF OHIO et al.) 22 September 2005 See abstract, figure 1-4.	1-8 9-21
A	WO 2004-001371 A2 (HYBRIZYME CORPORATION et al.) 31 December 2003 See abstract and pages 10-11.	1-21
A	WO 2006-079048 A2 (GENE EXPRESS, INC. et al.) 27 July 2006 See abstract.	1-21
PA	MIURA, A. et al, BMC Genomics, doi:10.11.1186/1471-2164-9-574. See abstract and page 3-4 of 14.	1-21
A	SIMI, L. et al. Clinica Chimica Acta, 2007, vol. 384, pages 149-154. See abstract.	1-21

☐ 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

16 FEBRUARY 2010 (16.02.2010)

Date of mailing of the international search report

17 FEBRUARY 2010 (17.02.2010)

Name and mailing address of the ISA/KR

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gu, Daejeon 302-701, Republic of Korea

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/038288**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:

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

I. Claims 1-8 are directed to a method for characterizing gene expression. II. Claims 9-22 are directed to a method to assess an effect of DNA polymorphisms on regulation of transcription.

The inventions listed as Groups I, II have very different steps comprising the method and the constituents (i.e. primer, target, hybridizing region etc.). The inventions listed as Groups I, II 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; they are separate inventions with distinct fields of search.

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/US2009/038288

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		WO 2006-079034 A3	27.07.2006

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2009/038288

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