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- (21) International Application Number: PCT/US2009/064370 (72) Inventor; and (75) Inventor/Applicant (for US only): HU, Valerie, Wailin [US/US]; 16610 Leopard Terrace, Rockville, MD 20854 (US).
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[Continued on next page]

(54) Title: COMPOSITIONS AND METHODS FOR IDENTIFYING AUTISM SPECTRUM DISORDERS

(57) Abstract: The compositions and methods described are directed to gene chips having a plurality of different oligonucleotides with specificity for genes associated with autism spectrum disorders. The invention further provides methods of identifying gene profiles for neurological and psychiatric conditions including autism spectrum disorders, methods of treating such conditions, and methods of identifying therapeutics for the treatment of such neurological and psychiatric conditions.

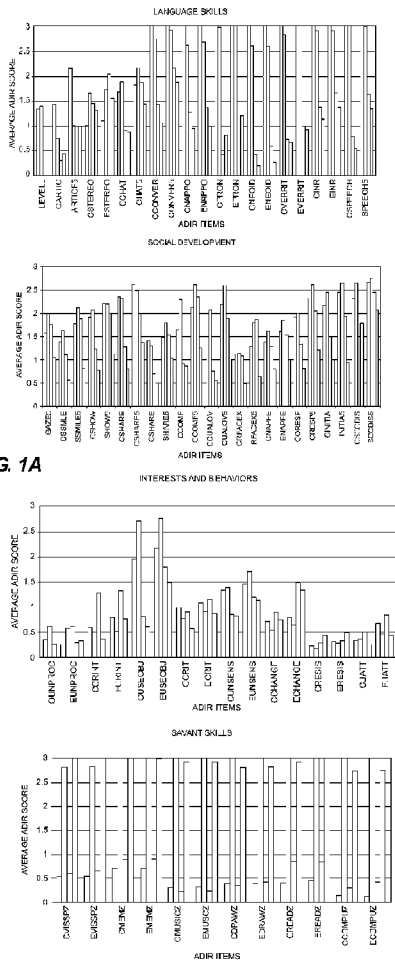


FIG. 1A



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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, 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.

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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)*)

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/064370**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

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

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

eKOMPASS(KIPO internal) & Keywords: autism, biomarker.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	The American Journal of Human Genetics, February 2008, vol.82, pp.477-488. See abstract, tables 2,3.	1,20
A	Prostaglandin, Leukotrienes and Essentials Fatty Acids, 2005, vol.73, pp.379-384. See the whole document.	1,20
A	Journal of Toxicology and Environmental Health, 2007, vol.70, pp.1723-1730. See the whole document.	1,20
A	Am J Clin Nutr,2004, vol.80, 1611-1617. See the whole document.	1,20

 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 SEPTEMBER 2010 (16.09.2010)

Date of mailing of the international search report

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Name and mailing address of the ISA/KR

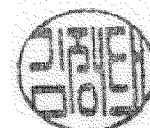
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2009/064370**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.: 2-19
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:

Claims 2-19 pertain to a method for treatment of the human body by therapy, as well as diagnostic methods, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

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 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 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.: 1, 20

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/US2009/064370

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
None			

This ISA found multiple inventions in this application as follows:

-Group 1: Claims 1, 20 (all partial) are drawn to a gene chip array and a kit having a plurality of different oligonucleotides with specificity for genes associated with at least one autism spectrum disorder, wherein the oligonucleotides are specific for the genes set out in table 3.

-Group 2: Claims 1, 20 (all partial) are drawn to a gene chip array and a kit having a plurality of different oligonucleotides with specificity for genes associated with at least one autism spectrum disorder, wherein the oligonucleotides are specific for the genes set out in table 7.

.....

-Group 13: Claims 1, 20 (all partial) are drawn to a gene chip array and a kit having a plurality of different oligonucleotides with specificity for genes associated with at least one autism spectrum disorder, wherein the oligonucleotides are specific for the genes set out in table 27.

-Group 14: Claims 1, 20 (all partial) are drawn to a gene chip array and a kit having a plurality of different oligonucleotides with specificity for genes associated with at least one autism spectrum disorder, wherein the oligonucleotides are specific for the genes set out in table 28.

The single general concept linking Groups 1-14 together is merely "a gene chips having a plurality of different oligonucleotides with specificity for genes associated with autism spectrum disorders". This common concept is, however, described in "The American Journal of Human Genetics, Vol.82, pp.477-488 (Christian R. Marshall et al., February 2008)" and, therefore, does not represent any contribution over the prior art.

Hence the inventions listed as Groups 1-14 do not relate to a single general inventive concept under PCT Rule 13.1 because the above mentioned common concept fails to make a contribution over the prior art within the meaning of PCT Rule 13.2.