Title: METHODS AND COMPOSITIONS FOR AUTISM RISK ASSESSMENT BACKGROUND

Abstract: Methods and compositions are provided for evaluating an individual for relative genetic risk for autism, for identifying a form of a genetic polymorphism that is linked to autism, and for evaluating whether a compound affects autism.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPQ(7) : C12P 19/34; C12Q 1/68; C07H 21/04
US CL. : 435/6, 91.1; 536/23.1
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)
U.S. : 435/6, 91.1; 536/23.1

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)
Medline, CAPLUS, East, ScienceDirect

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

[ ] See patent family annex.

[ ] Further documents are listed in the continuation of Box C.

Date of the actual completion of the international search

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer
Sarah Baicher
Telephone No. (571) 272.1600

Date of mailing of the international search report
19 Jan 2006

Form PCT/ISA/210 (second sheet) (April 2005)
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found un searchable (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.: 3  
     - 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:
       - No CRF provided for sequence listing.

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:
Please See Continuation 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 additional fees, this Authority did not invite payment of any 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, 2 and 12

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.

Form PCT/ISA/210 (continuation of first sheet(2)) (April 2005)
BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

Group 1, claims 1-2 and 12, a method of evaluating an individual for genetic risk for autism by genotyping SLC25A12.

Group 2, claims 4-11 and 14-21, nucleic acid molecules, eukaryotic cell and non-human animal comprising the nucleic acid.

Group 3, claim 13, use of genetic polymorphism for evaluating an individual for risk for autism.

Group 4, claim 22, method of evaluating whether a compound affects autism by detecting the expression of SLC25A12.

Further species election:

For group 1, the first species are considered to be each genotype, rs2056202 and rs2292813 and the second species are the primers, SEQ ID No. 5-8.

For group 2, the species are considered to be a set of primer pairs, SEQ ID No. 5-6, 7-8, and a nucleic acid sequence SEQ ID No. 1-4.

The first named invention, which will be searched, is Group 1, species rs2056202 and SEQ ID No. 5, claims 1-3 and 12.

The invention listed as Groups 1-2 do not relate to a single 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: The common technical features that joins all the inventions is the gene SLC25A12.

SAHEKI, et al. (Metab. Brain Dis. December 2002 17(4), pp. 335-346 teach detection of a mutation in SLC25A12 gene which causes neonatal intrahepatic cholestasis and citrin deficiency (see abstract). Thus, the technical feature linking the recited groups 1-4 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Thus, there is no special technical feature that joins the methods.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species do not share a significant structural element and each element does not belong to a recognized class of chemical compounds (see Al Annex B, part 1(f)).