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[Continued on next page]

(54) Title: PREDICTION AND PREVENTION OF PREECLAMPSIA

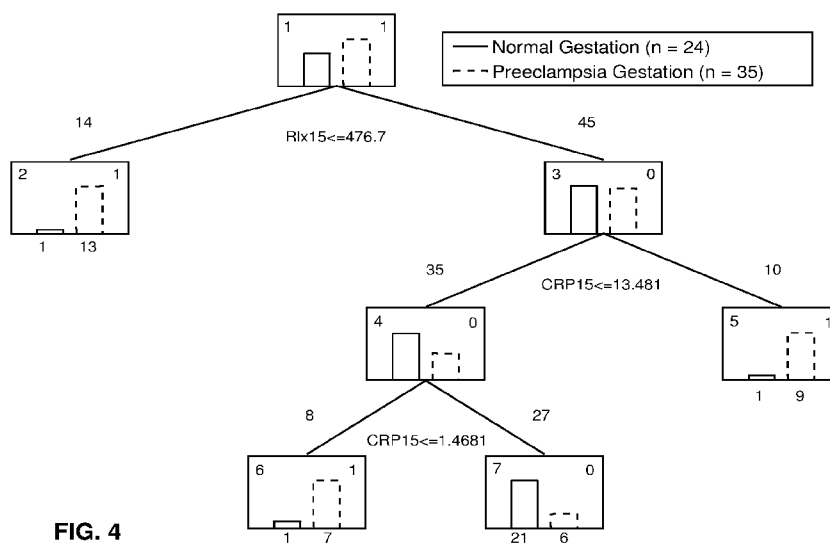


FIG. 4

(57) Abstract: The present disclosure relates to methods for assessing increased risk of preeclampsia in a pregnant woman. The methods described herein employ measuring relaxin levels, and optionally measuring C-reactive protein levels in a biological sample of a pregnant woman. The disclosure further encompasses methods of reducing risk of preeclampsia through administration of a pharmaceutical formulation of relaxin to a pregnant woman.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/65795

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 33/53; C07K 16/00 (2010.01)

USPC - 435/7.1; 530/388.15

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- 435/7.1; 530/388.15

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

USPC- 514/12; 530/389.1

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

PubWEST(PGPB,USPT,USOC,EPAB,JPAB), Google Scholar: PTA-8423, preeclampsia H2 relaxin quartile, pre-eclampsia, pregnancy-induced hypertension, HOP syndrome, EHP syndrome, HELLP syndrome

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0108572 A1 (UNEMORI) 8 May 2008 (08.05.2008) para [0010], [0015], [0037], [0055], [0058], [0065], [0067], [0081], [0107]	1-9, 11-21
Y	DECKER et al. Some effects of relaxin in obstetrics. <i>Obstet Gynecol</i> 1958, 12(1):37-46; pg 37, left col, para 4; pg 41, right col, The Effect of Relaxin in Toxemia of Pregnancy, para 1; pg 43, Case 2; pg 44, fig 3	1-9, 11-21
Y	SPENCER et al. First-trimester maternal serum PP-13, PAPP-A and second-trimester uterine artery Doppler pulsatility index as markers of pre-eclampsia. <i>Ultrasound Obstet Gynecol</i> 2007, 29:128-134; pg 129, left col para 1-2; pg 130, right col, para 1	5, 14-21
Y	NESS et al. Heterogeneous causes constituting the single syndrome of preeclampsia: a hypothesis and its implications. <i>Am J Obstet Gynecol</i> 1996, 175:1365-70; pg 1368, para 1-2	6-7, 19-20
Y	QIU et al. A prospective study of maternal serum C-reactive protein concentrations and risk of preeclampsia. <i>Am J Hypertens</i> 2004, 17:154-160; abstract	9
A	Hwang, et al. Maternal serum highly sensitive C-reactive protein in normal pregnancy and pre-eclampsia. <i>International Journal of Gynecology and Obstetrics</i> 2007, 98:105-109; Abstract, pg 107, Table 2	10

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 6 August 2010 (06.08.2010)	Date of mailing of the international search report 08 NOV 2010
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/65795

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 1-21, drawn to a method comprising monitoring H2 relaxin concentration in a sample from a pregnant woman.

Group II, claims 22-24, drawn to an anti-H2 relaxin monoclonal AB produced by the hybridoma PTA-8423, and a kit comprising said antibody.

***** 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 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.:

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.

..... Supplemental Box

Continuation of Box No. III

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:

The inventions of Group I do not include the inventive concept of an anti-H2 relaxin monoclonal AB produced by the hybridoma PTA-8423, as required by Group II.

The inventions of Group II do not include the inventive concept of correlating a level of H2 relaxin with preeclampsia, as required by Group I.

The inventions of Groups I-II share the technical feature of measuring H2 relaxin concentration in a sample. However, this shared technical feature does not represent a contribution over the prior art of US 2008/0108572 A1 (08 May 2008) to Unemori, et al. that discloses that "[s]erum rhRLX levels were measured by quantitative ELISA specific for human relaxin (H2) (para [0283]-[0284]). As said measuring H2 relaxin concentration in a sample was known at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

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