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Previous Correction:

see PCT Gazette No. 46/2001 of 15 November 2001, Section II

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: NOVEX POLYPEPTIDES, NUCLEIC ACIDS ENCODING SAME AND THEIR DIAGNOSTIC AND THERAPEUTIC USE

(57) Abstract: The present invention provides isolated NOVX polynucleotides and polypeptides encoded by the NOVX polynucleotides. Also provided are the antibodies that immunospecifically bind to a NOVX polypeptide or any derivative, variant, mutant or fragment of the NOVX polypeptide, polynucleotide or antibody. The invention additionally provides methods in which the NOVX polypeptide, polynucleotide and antibody are utilized in the detection and treatment of a broad range of pathological states, as well as to other uses.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/00299

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/435 A61K38/17 A61K39/00 A61K39/395 G01N33/53

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)

IPC 7 C07K C12N A61K G01N

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)

BIOSIS, EMBL, EPO-Internal, WPI Data, EMBASE, MEDLINE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EMBL [Online] epididymis specific; HE3 gene, 10 December 1993 (1993-12-10) KIRCHHOFF C. ET AL.: "H. sapiens mRNA for HE3 (beta)" retrieved from EMBL, accession no. X76386 XP002173500 cited in the application	1,5, 9-12,14
Y	abstract	13,15-20
X	& KIRCHHOFF CHRISTIANE ET AL.: "Major human epididymis-specific gene product, HE3, is the first representative of a novel gene family" MOLECULAR REPRODUCTION AND DEVELOPMENT, vol. 37, no. 2, 1994, pages 130-137, XP001008544	13,15-20 1,5, 9-12,14
Y	Abstract, Introduction, Figs. 1, 4, Discussion.	13,15-20
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in 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 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

"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

30 July 2001

Date of mailing of the international search report

02. 11. 01

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/00299

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	--- OSTERHOFF CAROLINE ET AL: "Molecular cloning and characterization of a novel human sperm antigen (HE2) specifically expressed in the proximal epididymis." BIOLOGY OF REPRODUCTION, vol. 50, no. 3, 1994, pages 516-525, XP001008567 ISSN: 0006-3363 abstract Abstract, Introduction, Results, Discussion.	1,5,9-20
Y	--- KIRCHHOFF CHRISTIANE ET AL: "A major mRNA of the human epididymal principal cells, HE5, encodes the leucocyte differentiation CDw52 antigen peptide backbone." MOLECULAR REPRODUCTION AND DEVELOPMENT, vol. 34, no. 1, 1993, pages 8-15, XP001008536 ISSN: 1040-452X the whole document	1,5,9-20
Y	--- C KIRCHLOF ET AL: "Cloning and analysis of mRNAs expressed specifically in the human epididymis" INTERNATIONAL JOURNAL OF ANDROLOGY, GB, BLACKWELL SCIENTIFIC PUBLICATIONS, OXFORD, vol. 2, no. 13, 1 April 1990 (1990-04-01), pages 155-167, XP002075040 ISSN: 0105-6263 Summary, Introduction, Discussion	1,5,9-20
Y	--- EP 0 440 321 A (IHF INST FUER HORMON UND FORTP) 7 August 1991 (1991-08-07) Claims and Sequence listing, also page 1 -page 5; examples 1-9	1,5,9-20
Y	--- KIRCHHOFF, C.: "Molecular Aspects of Epididymal Function and Sperm Maturation" CURRENT ADVANCES IN ANDROLOGY, PROC. INT. CONGR. ANDROL., 6TH, 1997, pages 253-259, XP001008538 the whole document -----	1,5,9-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/00299

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 1(e), 24, 5(e), (f), 6-8, 11 (fragment), 21-43
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 II Observations where unity of invention is lacking (Continuation of item 2 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 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, 5, 9-20, (all partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. Claims: 1,5,9-20, (all partially)

An isolated polypeptide comprising an amino acid sequence selected from the group consisting of : a) a mature form of the amino acid sequence given by SEQ ID NO: 2; various defined variants thereof; antibodies immunospecifically binding thereto; methods for determining the presence or amount of the polypeptide in a sample; the corresponding isolated nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising an amino acid sequence given by SEQ ID NO: 2; defined variants thereof; specifically SEQ ID NO: 1; Corresponding vectors; cells comprising the vectors; methods for determining the presence or amount of the corresponding nucleic acid in a sample.

2. Claims: 1,5,9-20, (all partially)

As for invention 1, but referring to SEQ ID NO: 4 and SEQ ID NO: 3.

3. Claims: 1,5,9-20, (all partially)

As for invention 1, but referring to SEQ ID NO: 6 and SEQ ID NO: 5.

4. Claims: 1,5,9-20, (all partially)

As for invention 1, but referring to SEQ ID NO: 8 and SEQ ID NO: 7

5. Claims: 1,5,9-20, (all partially)

As for invention 1, but referring to SEQ ID NO: 10 and SEQ ID NO: 9

6. Claims: 1,5,9-20, (all partially)

As for invention 1, but referring to SEQ ID NO: 12 and SEQ ID NO: 11

7. Claims: 1,5,9-20, (all partially)

As invention 1, but referring to SEQ ID NO: 14 and SEQ ID NO: 13

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

8. Claims: 1,5,9-20, (all partially)

Same as invention 1, but referring to SEQ ID NO: 16 and SEQ
ID NO: 15

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1(e),24,5(e),(f),6-8, 11 (fragment), 21-43

Claim 1 (e) refers to a fragment of a) through d) without further meaningful qualification.

Claims 2-4 are directed to obvious desiderata which are not clearly further defined, thus making a meaningful search impossible. The same applies to; claims 6-8, claim 5 part e) wherein neither the size of the portion nor its function are defined and also to its complement f). The fragment of claim 11 is also not searched for the same reasons as above. The antecedent reference claims are also thus search restricted.

Claim 21 is directed to a method for identifying a potential therapeutic agent for use in treatment of a pathology, defined by being related to aberrant expression or aberrant physiological interactions of the polypeptide of claim 1. No precise property or function has been ascribed to the above polypeptides, nor have any substances been even proposed to alter the property or function of the peptides. It is therefore not possible search even within the application for such a claim. The same applies, mutatis mutandis, to the subject-matter of claim 22, for a method of modulating the activity of the polypeptide of claim 1, the methods of treatment or prevention of pathology of claims 23-28, since the associated pathology has neither been clearly defined in the claims nor the application as a whole. This also applies to claims 29-34, for pharmaceutical compositions and formulations and kits containing same, as well as to claims 35-37, directed to the use of therapeutics in the manufacture of various medicaments and claims 38-39, directed to methods of screening for a modulator of activity or of latency or predisposition to a pathology associated with the polypeptide of claim 1. For the same reasons, since a precise medical indication is not present in the claims and there is no concrete definition in the specification, a meaningful search is not feasible.

Thus, the application provides neither concrete example of function, pathology, pharmaceuticals, nor methods of treatment. The application is thus considered to be so lacking in teaching under Art. 5 PCT and the claims considered to be so broad and unclear in scope under Art. 6 PCT, to render them lacking in support by the description that not even a partial search based on any information provided in the specification can be considered justified.

The applicant's attention is drawn to the fact that claims, or parts of 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. Application No

PCT/US 01/00299

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0440321	A	07-08-1991	
		DE 4002981 A1	08-08-1991
		DE 4038189 A1	04-06-1992
		AT 175719 T	15-01-1999
		DE 59109085 D1	25-02-1999
		DK 440321 T3	30-08-1999
		EP 0440321 A2	07-08-1991
		EP 0878544 A1	18-11-1998
		ES 2127192 T3	16-04-1999
		GR 3029608 T3	30-06-1999
