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- (81) **Designated States (national):** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
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(54) **Title:** PREVENTION AND TREATMENT OF SEXUAL AROUSAL DISORDERS

(57) **Abstract:** This invention relates generally to the field of urology. In particular, the invention provides a method for preventing or treating male erectile dysfunction or female sexual arousal disorder, which method comprises administering an effective amount of vascular endothelial growth factor (VEGF), brain-derived neurotrophic factor (BDNF), basic fibroblast growth factor (bFGF), or a functional derivative or fragment thereof, or a nucleic acid encoding said VEGF, BDNF or bFGF, or functional derivative or fragment thereof, or an agent that enhances production and/or erection or sexual arousal stimulating function of said VEGF or BDNF or bFGF to a mammal, wherein such prevention or treatment is desirable, thereby preventing or treating said male erectile dysfunction or female sexual arousal disorder in said mammal. Combinations, combinatorial methods and kits for preventing or treating male erectile dysfunction or female sexual arousal disorder are also provided.

INTERNATIONAL SEARCH REPORT

International Application No

P US 01/22970

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K38/19 A61K38/18 A61K48/00 A61P15/00 //(A61K38/19, 38:18)

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 A61K

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)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	LEE M-C ET AL: "THE EFFECT OF VASCULAR ENDOTHELIAL GROWTH FACTOR ON A RAT MODEL OF ARTERIAL IMPOTENCE" JOURNAL OF UROLOGY, BALTIMORE, MD, US, vol. 163, no. 4, SUPPL, April 2000 (2000-04), page 198, AB877 XP001127486 ISSN: 0022-5347 *abstract*	1,2,5, 11,15

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

17 January 2003

Date of mailing of the international search report

19. 05. 2003

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INTERNATIONAL SEARCH REPORT

International Application No

P US 01/22970

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BURCHARDT M ET AL: "Expression of messenger ribonucleic acid splice variants for vascular endothelial growth factor in the penis of adult rats and humans" BIOLOGY OF REPRODUCTION, SOCIETY FOR THE STUDY OF REPRODUCTION, CHAMPAIGN, IL, US, vol. 60, no. 2, February 1999 (1999-02), pages 398-404, XP002142278 ISSN: 0006-3363 page 403, column 1, paragraph 2 ---	1,2,5,6, 11-15
P,X	WO 01 24809 A (UNIV DUKE) 12 April 2001 (2001-04-12) page 5, line 21 -page 6, line 11; claims 1-3,6-10 ---	1,2,5, 11-15,21
P,X	WO 00 43029 A (UNIV COLUMBIA) 27 July 2000 (2000-07-27) page 4 -page 5; claims ---	1,2,5-7, 11-15
E	WO 01 68125 A (CHIRON CORP ;WHITEHOUSE MARTHA JO (US)) 20 September 2001 (2001-09-20) page 1, line 2 - line 5 page 11, line 14 - line 17 page 14, line 2 - line 20; claims -----	1,2,5, 9-13,15, 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/22970

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:

Although claims 1,2,5-15,21,22 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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:

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, 5-15, 21-22 (all partially), 2

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: 2, partially: 1,5-15,21-22

a pharmaceutical composition of VEGF for the treatment of male erectile dysfunction or female sexual arousal disorder.

2. Claims: 3, partially: 1,5-22

a pharmaceutical composition of BDNF, alone or in combination with an agent that stimulates male erectile dysfunction or female sexual arousal disorder, for the treatment of male erectile dysfunction or female sexual arousal disorder.

3. Claims: 4, partially: 1,5-22

a pharmaceutical composition of bFGF, alone or in combination with an agent that stimulates male erectile dysfunction or female sexual arousal disorder, for the treatment of male erectile dysfunction or female sexual arousal disorder.

4. Claims: 16-20 (partially)

a pharmaceutical composition of VEGF in combination with an agent that stimulates male erectile dysfunction or female sexual arousal disorder.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1,2,5-15,21,22 relate to an extremely large number of possible compounds, namely "functional derivative", "fragment thereof", "agent". Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search for the first invention has been carried out for those parts of the claims which appear to be supported and disclosed, namely VEGF in relation to the treatment of male erectile dysfunction or female sexual arousal disorder; and with due regard to the general idea underlying the invention.

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

International Application No

P . JS 01/22970

Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
WO 0124809	A	12-04-2001	AU 7733800	10-05-2001
			CA 2386480	12-04-2001
			EP 1223957	24-07-2002
			WO 0124809	12-04-2001

WO 0043029	A	27-07-2000	AU 2623700	07-08-2000
			CA 2360058	27-07-2000
			EP 1150698	07-11-2001
			JP 2003501345	14-01-2003
			WO 0043029	27-07-2000

WO 0168125	A	20-09-2001	AU 5082101	24-09-2001
			WO 0168125	20-09-2001
			US 2002032153	14-03-2002
