

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 February 2002 (07.02.2002)

PCT

(10) International Publication Number
WO 02/010338 A3

(51) International Patent Classification⁷: **C12Q 1/68**,
C12P 19/34, C07H 21/02

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(21) International Application Number: PCT/US01/23861

(22) International Filing Date: 31 July 2001 (31.07.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/222,039 31 July 2000 (31.07.2000) US

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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, US, UZ, VN, YU, ZA,
ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD,
TG).

Published:

— with international search report

(88) Date of publication of the international search report:
1 August 2002

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

(54) Title: EXPRESSION OF GAGE/PAGE-LIKE PROTEIN IN BENIGN PROSTATIC HYPERPLASIA

(57) Abstract: The invention relates generally to the changes in gene expression in Benign Prostatic Hyperplasia (BPH). The invention relates specifically to methods of using a human gene or protein which corresponds to a mRNA species that is differentially expressed in BPH compared to normal prostate tissue for diagnostic or screening purposes.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/23861

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/68; C12P 19/34; C07H 21/02

US CL : 435/6, 91.1, 91.2; 536/23.1, 24.3, 24.31, 24.33

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, 91.2; 536/23.1, 24.3, 24.31, 24.33

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)

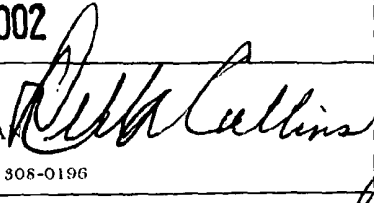
Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----	BRINKMANN et al. PAGE-1, an X-chromosome linked GAGE-like gene that is expressed in normal and neoplastic prostate, testis and uterus. Proc. Natl. Acad. Sci. USA. September 1998, Vol. 95, pages 10757-10762, especially page 10761, column 2, lines 18-26.	1-3, 5, 6, 9 ----
Y		4
Y	US 6,034,218 A (REED et al) 07 March 2000, col. 8, lines 24-25 and col. 13, lines 57-67.	1-6, 9

☐ 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	"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
"E" earlier document published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"A" document member of the same patent family
"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 13 DECEMBER 2001	Date of mailing of the international search report 25 JAN 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JEFFREY FREDMAN 
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/23861

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international 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 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:

Please See Extra 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.:
1-6, 9

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/23861

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

EAST, MEDLINE, BIOSIS, CAPLUS

search terms: diagnose, identify, determine, prostate, cancer, carcinoma, tumor, benign, hyperplasia, bph, urine, blood, lymphocyte, page-1, jt463726, nucleic, DNA, RNA, oligo

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-6, 9, drawn to nucleic acid methods for diagnosis of prostate disease using JT463726.

Group II, claim(s) 1-4, 7-9, drawn to protein based methods for diagnosis of prostate disease using JT463726.

Group III, claim(s) 10-11, drawn to methods of screening for agents which affect JT463726.

Group IV, claim(s) 12, 16, drawn to methods of treatment using an agent which affects JT463726.

Group V, claim(s) 13-15, drawn to agents which affect JT463726.

Group VI, claim(s) 17-18, drawn to a nonhuman transgenic animal which comprises JT463726.

Group VII, claim(s) 19, drawn to a nucleic acid which encodes the JT463726 sequence or at least 6 amino acids or is 60% identity with SEQ ID NO: 1.

Group VIII, claim(s) 20, drawn to antibodies against the JT463726 sequence or at least 6 amino acids or is 50% identity with SEQ ID NO: 2.

Group IX, claim(s) 21, drawn to JT463726 proteins or at least 6 amino acids or is 50% identity with SEQ ID NO: 2.

The inventions listed as Groups I-IX 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 Groups lack a special technical feature because Brinkmann et al (Proc. Natl. Acad. Sci> USA (September 1998) 95:10757-10762) teaches a sequence which comprises 490 nucleotides which are 100% identical to SEQ ID NO: 1 as well as 102 amino acids with 100% identity. In view of the absence of a special technical feature related to the nucleic acid and amino acid sequences, there is no single inventive concept.