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(54) Title: MP21S AS MODIFIERS OF THE p21 PATHWAY AND METHODS OF USE

(57) Abstract: Human MP21 genes are identified as modulators of the p21 pathway, and thus are therapeutic targets for disorders associated with defective p21 function. Methods for identifying modulators of p21, comprising screening for agents that modulate the activity of MP21 are provided.

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US03/24575

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC(7) : C12Q 1/00, 1/68; G01N 33/53  
 US CL : 435/4, 6, 7.1  
 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. : 435/4, 6, 7.1

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)  
 Please See Continuation Sheet

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,762,706 (McCORMICK et al) 9 August 1988, see especially Brief Summary Text, paragraphs 36, 40, 49 and 52 as well as Detailed description Text paragraph 42.	1, 4-5, 7

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 application or patent 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	"&" 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: 02 September 2005 (02.09.2005)  
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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/24575

## 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.  Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claim 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.  Claim 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 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 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-in-part, 4-5, 7
- 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

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

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

The inventions listed as Groups 1-7 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:

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

Group 1, claim(s) 1-in-part, 4-5 and 7 drawn to a method of identifying a candidate p21 pathway modulating agent comprising providing an assay system comprising an MP21 polypeptide, detecting a test agent-biased activity.

Group 2, claim(s) 1-in-part, 2-3, 6, 8-10, drawn to a method of identifying a candidate p21 pathway modulating agent comprising providing an assay system comprising an MP21 polynucleotide and polypeptide/cultured cells.

Group 3, claim(s) 1, 11-in-part, 13-in-part, as it is drawn to cultured cells, 15, 16-in-part, 17, 20-in-part as it is drawn to cell culture, 21, 22-in-part, drawn to a method of identifying a candidate p21 pathway modulating agent comprising providing a cultured cell assay system and contacting said system with a test agent which specifically binds to a MP21 polypeptide and restores p21 function, further comprising administering the identified candidate modulator to cultured cells.

Group 4, claim(s) 1, 11-in-part, 13-in-part, as it is drawn to cultured cells, 16-in-part, 17, 20-in-part, as it is drawn to cell culture, 21, 22-in-part, drawn to a method of identifying a candidate p21 pathway modulating agent comprising providing a cultured cell assay system and contacting said system with a test agent which is a nucleic acid modulator/a nucleic acid that specifically binds a MP21 nucleic acid, further comprising administering the identified candidate modulator to cultured cells.

Group 5, claim(s) 1, 11-in-art, 12, 13-in-part, as it is drawn to an animal model, 14-15, 16-in-part, 18-19, 20 as it is drawn to an animal model 21, 22-in-part, drawn to a method of identifying a candidate p21 pathway modulating agent, further comprising administering the identified candidate to an assay system comprising a mouse and contacting said system with a test agent which specifically binds to a MP21 polypeptide and restores p21 function.

Group 6, claim(s) 1, 11-in-art, 12, 13-in-part, as it is drawn to a animal model, 14-15, 16-in-part, 18-19, 20-in-part as it is drawn to an animal model 21, 22-in-part, drawn to a method of identifying a candidate p21 pathway modulating agent, further comprising administering the identified candidate to an assay system comprising a mouse and contacting said system with a test agent which is a nucleic acid modulator/a nucleic acid that specifically binds a MP21 nucleic acid.

Group 7, claim(s) 23-25, drawn to a method for diagnosing a disease comprising probing for MP21 expression.

The inventions listed as Groups 1-7 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:

An international stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered

# INTERNATIONAL SEARCH REPORT

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as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1, claims 1-in-part, 4-5 and 7 form a single general inventive concept.  
Groups 2-7 are drawn to different methods and therefore are broken out as separate groups.

**Continuation of B. FIELDS SEARCHED Item 3:**  
MEDLINE, CAPLUS, BIOSIS, USPATFUL  
search terms: p21, antibody, antibody assay