Abstract: Provided are methods for determining a prognosis for an individual suspected of having or diagnosed with cancer, where a high CD24 / low FLJ 13639 ratio indicates an unfavorable prognosis. Also provided are methods for enhancing the activity of chemotherapeutic agents, and isolated, purified FLJ13639 proteins for use in improving the prognosis of an individual and for enhancing the activity of chemotherapeutic agents.
### A CLASSIFICATION OF SUBJECT MATTER

**IPC(8) -** C12P 19/34, C07H 21/02 (2008.01)

**USPC -** 435/91.1, 536/23.1

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)

<table>
<thead>
<tr>
<th>IPC(8)</th>
<th>C12P 19/34, C07H 21/02</th>
</tr>
</thead>
</table>

**USPC -** 435/91 1, 9 2, 9 21, 514/44, 536/23 1, 23 5

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

### C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>US 2004/0005596 A1 (Li et al) 8 January 2004 (08 01 2004) para [0025], [0230], [0233]:[0234], [0236]</td>
<td>1-8</td>
</tr>
<tr>
<td>A</td>
<td>WO 01/81586 A2 (Meyers) 01 November 2001 (01 11 2001) Fig 1, pg 64 in 16-19</td>
<td>1-8</td>
</tr>
</tbody>
</table>

* 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 application or patent 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 be inventive step when the document is taken alone.

**Y** document of particular relevance, the claimed invention cannot be considered to be 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.

Further documents are listed in the continuation of Box C.

### D

Date of the actual completion of the international search: 28 February 2008 (28 02 2008)

Date of mailing of the international search report: 12 JUN 2008

Name and mailing address of the ISA/US:

**Mail Stop PCT, Attn ISA/US, Commissioner for Patents**

**PO Box 1450,Alexandria, Virginia 22313-1450**

**Facsimile No 571-273-3201**

Authorized officer: Lee W Young

Form PCT/ISA/2 10 (second sheet) (April 2007)
**Box No. 1  Nucleotide and/or amino acid sequencers) (Continuation of item 1b of the first sheet)**

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of:

   a. type of material
      - [X] a sequence listing
      - [ ] table(s) related to the sequence listing

   b. format of material
      - [X] on paper
      - [ ] in electronic form

   c. time of filing/furnishing
      - [X] contained in the international application as filed
      - [ ] filed together with the international application in electronic form
      - [ ] furnished subsequently to this Authority for the purposes of search

2. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments
INTERNATIONAL SEARCH REPORT

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 D Claims Nos because they relate to subject matter not required to be searched by this Authority, namely

2 D 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 D 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

The inventions listed do not relate to a single general inventive concept under PCT Rule 13.1 According to PCT Rule 13.2, unity of invention exists only when the same or corresponding technical feature is shared by all claimed inventions

—see extra sheet for further discussion—

1 1 As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2 1 As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees

3 1 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  x 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

Claims 1-8 directed toward a method of determining the prognosis of an individual diagnosed with or suspected of having cancer restricted to SEQ ID NO 1 SEQ ID NO 6

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

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)
Continuation of Box No III Observations where unity of invention is lacking

Group I Claims 1-8 are directed toward a method of determining the prognosis of an individual diagnosed with or suspected of having cancer by measuring the amount of CD24 mRNA or CD24 protein in the sample, measuring the amount of FLJ13639 mRNA or FLJ13639 protein in the sample and comparing the amount of CD24 mRNA to the amount FLJ13639 mRNA, or comparing the amount CD24 protein to the amount of FLJ13639 protein to obtain a CD24 toFLJ13639 expression ratio wherein RT-PCR of FLJ13639 mRNA amplifies a cDNA comprising the sequence of SEQ ID NO 1 and/or RT-PCR of the CD24 mRNA amplifies a cDNA comprising the sequence of SEQ ID NO 6

Group II Claims 9-20 are directed toward an isolated, purified protein comprising the sequence of SEQ ID NO 2 (Human FLJ13639 P1 protein) and SEQ ID No 5 (a synthetic P1 protein) and a method of administering FLJ13639 P1 protein so that levels of protein may be analyzed

The inventions listed do not relate to a single general inventive concept under PCT Rule 13 1 According to PCT Rule 13 2, unity of invention exists only when the same or corresponding technical feature is shared by all claimed inventions The cDNAs represent by SEQ ID Nos 1 and 6 and the protein sequences represented by SEQ ID NOS 2 and 5 are deemed to lack unity of invention because are not so linked as to form a single general inventive concept under PCT Rule 13 1 The different amino acid sequences represented by the amino acid content of the subspecies of proteins are different structures that are not common to one another but are different because they are composed of unique amino acid sequences In order for the claims of Group I to be practiced as described, at least levels of cDNA represented by SEQ ID Nos 1 and 6 must be compared or the levels of both CD24 protein and P1 protein must be compared as represented by SEQ ID Nos 2 and 5 Therefore, at least two separate inventions are defined by the analysis of cDNA or protein

In this case, the first named invention and first named species that will be searched without additional fees is Group I represented by Claims 1-8 directed toward a method of determining the prognosis of an individual diagnosed with or suspected of having cancer by measuring the amount of CD24 and FLJ1 3639 mRNA in the sample and comparing the amount of CD24 mRNA to the amount FLJ13639 mRNA, wherein RT-PCR of FLJ13639 mRNA amplifies a cDNA comprising the sequence of SEQ ID NO 1 and/or RT-PCR of the CD24 rRNA amplifies a cDNA comprising the sequence of SEQ ID NO 6

In order for more than one species to be examined, the appropriate additional examination fees must be paid