COMPOSITIONS AND METHODS FOR TREATING CANCERS

35/00

Composition and methods for treating solid and hematological cancers, including Acute Myeloid Leukemia (AML), are provided herein. The methods include administering truncated, dominant-negative, forms of Galectin-3.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61 K 38/1 7; A61 P 35/00, 35/02; G01 N 33/574 (2017.01)
CPC - A61 K 38/1 72, 38/1 7, 38/1 709; G01 N 33/574

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)

See Search History document

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

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

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>
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<tbody>
<tr>
<td>X</td>
<td>US 2015/0157691 (T E X A S T E C H U N I V E R S I T Y S Y S T E M) June 11, 2015;</td>
<td>1, 3/1, 4/1, 5/1, 10/4/1,</td>
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<td></td>
<td>paragraphs [0012], [0024]-[0025], [0034], [0036], [0065].</td>
<td>11/10/4/1, 12/1 1/10/4/1</td>
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<td></td>
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<td>13/12/1 1/10/4/1</td>
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<tr>
<td>Y</td>
<td>SONG, et al., Galectin-3 Mediates Nuclear β-Catenin Accumulation And Wnt Signaling</td>
<td>13/12/1 1/10/4/1</td>
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<tr>
<td></td>
<td>In Human Colon Cancer Cells By Regulation Of GSK-33 Activity. Cancer Res. Author Manuscript</td>
<td>14/12/1 1/10/4/1</td>
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<td>15 February 2009, Vol. 69, pages 1-16, doi:10.1158/0008-5472.CAN-08-4153;</td>
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<tr>
<td></td>
<td>abstract; page 5, third paragraph; page 8, second paragraph.</td>
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<td>Y</td>
<td>MIRANDOLA, et al., Anti-Galectin-3 Therapy: A New Chance For Multiple Myeloma And</td>
<td>14/12/1 1/10/4/1</td>
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<td></td>
<td>Ovarian Cancer?; International Reviews Of Immunology, 2014, Vol. 33, pages 417-427,</td>
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<td></td>
<td>DOI: 10.3109/08930068.2014.91 1855; abstract; page 4; page 422, fourth paragraph;</td>
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<td>page 424, first paragraph.</td>
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<td>A</td>
<td>US 2003/0054982 (JARVIS, et al.) March 20, 2003; paragraphs [0022], [0041], [0042],</td>
<td>2, 3/2, 4/2, 5/2, 6/5/1-2,</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* "A" special category of cited documents:
  - "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
  - "G" document member of the same patent family

Date of the actual completion of the international search 12 August 2017 (12.08.2017)

Date of mailing of the international search report 12 SEP 2017

Name and mailing address of the ISA/ Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

PCT Helpdesk: 571-272-4300
PCT DSP: 571-272-7774
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<td>A</td>
<td>WO 2014/127275 A2 (RAZ, et al.) August 21, 2014; paragraph [0040].</td>
<td>2, 3/2, 4/2, 5/2, 6/5/2, 10/4/2, 11/10/4/2, 12/1/1/10/4/2, 13/12/1/1/10/4/2, 14/12/1/1/10/4/2</td>
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<td>A</td>
<td>US 2004/0023855 A1 (JOHN, et al.) February 5, 2004; paragraphs [0140]-[0141].</td>
<td>2, 3/2, 4/2, 5/2, 6/5/2, 10/4/2, 11/10/4/2, 12/1/1/10/4/2, 13/12/1/1/10/4/2, 14/12/1/1/10/4/2</td>
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<td>A</td>
<td>WO 2013/151666 A2 (MODERNA THERAPEUTICS) October 10, 2013; claim 2.</td>
<td>6/5/1</td>
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<tr>
<td>A</td>
<td>WO 2015/052345 A1 (UNIVERSITAT FUR BODENKULTUR WIEN) April 16, 2015; page 5, lines 19-21.</td>
<td>6/5/1</td>
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</table>
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.:
   - 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.: 7-9, 15-25
   - because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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This International Searching Authority found multiple inventions in this international application, as follows:

*"-Please See Supplemental Page-"."*

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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 additional fees, this Authority did not invite payment of additional fees.

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 **1-6, 10-14, restricted to SEQ ib NOs: 5 and 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/2 I0 (continuation of first sheet (2)) (January 201 5)
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 I. Claims 1 (in-part), 2 (in-part), 3 (in-part), 4 (in-part), 5 (in-part), 6 (in-part), 10 (in-part), 11 (in-part), 12 (in-part), 13 (in-part), 14 (in-part), 15 (in-part), 16 (in-part), 17 (in-part), 22 (in-part) and 23 (in-part), limited to SEQ ID NOs: 5 and 6 are directed toward a protein; a polynucleotide encoding the protein, and a pharmaceutical composition comprising the protein and method of treating cancer therewith.

Group II. Claims 1 (in-part), 2 (in-part), 3 (in-part), 4 (in-part), 5 (in-part), 6 (in-part), 10 (in-part), 11 (in-part), 12 (in-part), 13 (in-part), 14 (in-part), 15 (in-part), 16 (in-part), 17 (in-part), 22 (in-part) and 23 (in-part), limited to SEQ ID NOs: 7 and 8 are directed toward a protein; a polynucleotide encoding the protein, and a pharmaceutical composition comprising the protein and method of treating cancer therewith.

Group III. Claim 26 is directed toward a method of treating cancer, comprising: administering a therapeutically effective amount of a protein having the amino acid sequence of SEQ ID NO: 3.

The inventions listed as Groups I-III 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: the special technical features of Group I include SEQ ID NO: 5, not present in either of Groups II or III; the special technical features of Group II include SEQ ID NO: 7, not present in either of Groups I or III; the special technical features of Group III include wherein the cancer is not multiple myeloma, not present in either of Groups I or II.

Groups I-III share the technical features including: a method of treating cancer, comprising administering to a subject a therapeutically effective amount of a protein having a sequence at least 95% identical to SEQ ID NO: 5 or SEQ ID NO: 7. Groups I and II share the technical features including: a pharmaceutical composition comprising the protein and a pharmaceutically acceptable carrier; and a polynucleotide encoding the protein.

However, these shared technical features are previously disclosed by US 2003/0054982 A1 to Jarvis et al. (hereinafter ‘Jarvis’).

Jarvis discloses a method of treating cancer, comprising administering a therapeutically effective amount of a protein (a method of treating cancer, comprising administering a therapeutically effective amount of a protein; abstract); a protein having an amino acid sequence (a protein having an amino acid sequence; paragraphs [0022], [0041]); at least 95% identical to SEQ ID NO: 5 (comprising SEQ ID NO: 1 (at least 95% identical to SEQ ID NO: 5); paragraphs [0041], [0042]; wherein SEQ ID NO: 1 is 100% identical to Applicants’ SEQ ID NO: 5) a pharmaceutical composition comprising: the protein, and a pharmaceutically acceptable carrier (a pharmaceutical composition comprising: the protein, and a pharmaceutically acceptable carrier; abstract); and a polynucleotide encoding the protein (DNA (a polynucleotide) encoding the protein; paragraph [0077]).

Since none of the special technical features of the Groups I-III inventions is found in more than one of the inventions, and since all of the shared technical features are previously disclosed by the Jarvis reference, unity of invention is lacking.