
Declarations under Rule 4.17:
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(h))
— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(ii))

Published:
— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
— with sequence listing part of description (Rule 5.2(a))

Date of publication of the international search report: 6 April 2017
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 sequence listing:
   a. ☑ forming part of the international application as filed:
      ✔ in the form of an Annex C/ST.25 text file.
      ☑ on paper or in the form of an image file.
   b. ☐ furnished together with the international application under PCT Rule 32er. 1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
   c. ☑ furnished subsequent to the international filing date for the purposes of international search only:
      ☑ in the form of an Annex C/ST.25 text file (Rule 32er. 1(a)).
      ☑ on paper or in the form of an image file (Rule 32er. 1(b) and Administrative Instructions, Section 713).

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

3. Additional comments:
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 47/48, C07K 16/00, C07K 16/30, C07K 16/28, A61K 39/395 (2016.01)
CPC - C07K 16/30, C07K 16/3023, C07K 16/28, C07K 16/3069, C07K 16/18, C07K 16/2809, A61K 47/48384

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(8) - A61K 47/48, C07K 16/00, C07K 16/30, C07K 16/28, A61K 39/395 (2016.01)
CPC - C07K 16/30, C07K 16/3023, C07K 16/28, C07K 16/3069, C07K 16/18, C07K 16/2809, A61K 47/48384

Documentation searched beyond 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)

PubWEST/PGPB, LISP, U.SOC, EPAB, JPAF; PatBase, Google/Scholar: Pyrrolobenzodiazepine, PBD1, anti-PD-1 antibody, anti-HL-L1 antibody, pembrolizumab, nivolumab, pidilizumab, avelumab, atezolizumab, durvalumab, SNCA, alpha-synuclein, NACP, Non-A4 component of amyloid precursor, Non-A beta component of AD amyloid, PARK1, PARK4, PD1, PD-1

C. DOCUMENTS CONSIDERED D 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>X</td>
<td>WO 2015/031693 A1 (STEM CENTRX INC., et al.) 05 March 2015 (05.03.2015) claim 15, pg 2, 6, 10, 48, 49, 92, 100, 128</td>
<td>38-45, 63, 67-78</td>
</tr>
<tr>
<td>Y</td>
<td>Schalper, et al. Programmed death-1/programmed death-1 ligand axis as a therapeutic target in oncology: current insights. Journal of Receptor, Ligand and Channel Research ePub 23 December 2014: 1-7; Abstract, pg 2, col 1; pg 4, Table 2; pg 5, col 2</td>
<td>70-72, 76-78</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

- 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 claimed 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

- "Y" 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

Date of the actual completion of the international search
04 January 2017

Date of mailing of the international search report
06 FEB 2017

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
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Authorized officer: Lee W. Young
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PCT DSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/47870

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. ☐ 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. 6-22, 46-62
   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:

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:

Group I: Claims 1-5, 23, 24, 38-45, 63, 67-78, directed to a method comprising administering an anti-DLL3 ADC.

Group II: Claims 25-37, 64-66, directed to a lyophilized composition comprising the antibody drug conjugate (ADC) of the formula Ab-[L-D]n (claims 25-37) and an anti-DLL3 ADC of the specified formula (claims 64-66).

*************** See Supplemental Sheet to continue *******

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 covered by claims Nos.: 1-5, 23, 24, 38-45, 63, 67-78

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)) (January 2015)
In Continuation of Box III. Observations where unity of invention is lacking:

The inventions listed as Groups I and II 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:

Special Technical Features
The inventions of Group II do not include the shared or common technical feature of a method comprising administering an anti-DLL3 ADC, as required by Group I.

The inventions of Group I do not include the shared or common technical feature of a lyophilized composition comprising an anti-DLL3 ADC or an anti-DLL3 ADC of the specified formula, as required by Group II.

Common Technical Features
The inventions of Groups I and II share the technical feature of an anti-DLL3 ADC. The inventions of Group I and some inventions of Group II share the technical feature of a method for treating cancer by administering the anti-DLL3 ADC to the subject. However, these shared technical features do not represent a contribution over prior art as being anticipated by WO 2015/031693 A1 to STEM CENTRX INC [US], et al. (05 March 2015) (hereinafter "STEM CENTRX"). STEM CENTRX discloses an anti-DLL3 ADC (claim 1, Fig 4, pg 50, ADC 5) and a method for treating cancer by administering the anti-DLL3 ADC to the subject (pg 2, "the present invention provides novel delta-like ligand 3 (or DLL3) site specific conjugates comprising pyrrolobenzodiazepine ("PBD") payloads that effectively target tumor cells and/or cancer stem cells and may be used to treat patients suffering from a wide variety of malignancies"). As said technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Groups I and II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.