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Published:

- with international search report (Art. 21(3))
- with sequence listing part of description (Rule 5.2(a))

(88) Date of publication of the international search report:

24 October 2024 (24.10.2024)

(54) Title: ANTI-CD3 ANTIBODIES AND METHODS FOR THEIR USE

(57) Abstract: The present invention relates to novel anti-CD3 antibodies (as monoclonal antibodies or as used in other formats, such as bispecific or multi-specific formats) and compositions comprising such antibodies or cells activated, by such antibodies for use in treating disorders associated with CD3, such as human cancer therapy.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/016863

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c 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 sequence listing:

a. ☒ forming part of the international application as filed.

b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.1(a)),

☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

2. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this report has been established to the extent that a meaningful search could be carried out without a WIPO Standard ST.26 compliant sequence listing.

3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/016863

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.:
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:

-Please See Supplemental Page-

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.:
1-30, SEQ ID NO: 2 (VH CDR3 sequence), SEQ ID NO: 60 (VL CDR3 sequence), SEQ ID NO: 118 (heavy CVR sequence),
SEQ ID NO: 176 (light CVR sequence), Clust 1.1 (SMH cluster).

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/016863

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. C07K 16/28; C07K 16/46 (2023.01)

ADD.

CPC - INV. C07K 16/2809; C07K 16/2803; C07K 16/2896; C07K 16/468; C07K 2317/31

ADD. A61K 2039/505; C07K 2317/52; C07K 2317/565; C07K 2317/92

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 documentDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History documentElectronic database consulted during the international search (name of database and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2017/0298148 A1 (UHLIN MICHAEL) 19 October 2017; claim 110	1-30
A	US 2014/0056878 A1 (ANAPTYSBIO INC.) 27 February 2014; paragraph [0037]	1-6, 11-16, 17-25
A	WO 2022/132929 A2 (VERA THERAPEUTICS INC.) 23 June 2022; claims 1 and 2	1-30
A	US 2017/0306044 A1 (ENGMAB AG) 26 October 2017; paragraph [0124], claims 1 and 4	6-10, 26-30

☐ 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

"D" document cited by the applicant in the international application

"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 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

"&"

document member of the same patent family

Date of the actual completion of the international search

15 May 2024 (15.05.2024)

Date of mailing of the international search report

JUL 23 2024

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/016863

-Continued From Box No. III: 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.

Groups I+, Claims 1-30, SEQ ID NO: 2 (VH CDR3 sequence), SEQ ID NO: 60 (VL CDR3 sequence), SEQ ID NO: 118 (heavy CVR sequence), SEQ ID NO: 176 (light CVR sequence), Clust 1.1 (SMH cluster) are directed towards anti-CD3 antibody or antibody fragments.

The anti-CD3 antibody or antibody fragments of Claims 1-30 (each in part) are believed to encompass the first named invention of Groups I+ and are the claims that will be searched without fee to the extent that they encompass SEQ ID NO: 2 (VH CDR3 sequence), SEQ ID NO: 60 (VL CDR3 sequence), SEQ ID NO: 118 (heavy CVR sequence), SEQ ID NO: 176 (light CVR sequence), Clust 1.1 (SMH cluster). This first named invention of Group I+ has been selected to encompass the first species of each of the genera found in claims 1-4 and 6 based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines.

Applicant is invited to elect additional VH CDR3 sequence(s); VL CDR3 sequence(s); heavy CVR sequence(s); light CVR sequence(s); and SMH cluster(s) to be searched. Additional VH CDR3 sequence(s); VL CDR3 sequence(s); heavy CVR sequence(s); light CVR sequence(s); and SMH cluster(s) will be searched upon the payment of additional fees. Applicants must specify the searchable claims that encompass any additionally elected VH CDR3 sequence(s); VL CDR3 sequence(s); heavy CVR sequence(s); light CVR sequence(s); and SMH cluster(s). Applicants must further indicate, if applicable, the claims which encompass the first named invention, if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "+" group(s) will result in only the first claimed invention to be searched/examined. Exemplary elections would be SEQ ID NO: 3 (VH CDR3 sequence), SEQ ID NO: 61 (VL CDR3 sequence), SEQ ID NO: 119 (heavy CVR sequence), SEQ ID NO: 177 (light CVR sequence), Clust 1.2 (SMH cluster).

Groups I+ share the technical features including: an anti-CD3 antibody or antibody fragment comprising a heavy chain variable region. These shared technical features are previously disclosed by US 2017/0298148 A1 to Michael Uhlin, et al. (hereinafter "Uhlin").

Uhlin discloses an anti-CD3 antibody or antibody fragment comprising a heavy chain variable region (anti-CD3 antibody with heavy chain variable region sequence; claim 104).

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