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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))

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19 October 2023 (19.10.2023)

(54) Title: MOLECULES THAT BIND TO NEUTROPHIL ELASTASE POLYPEPTIDES

(57) Abstract: This document provides methods and materials involved in binding a binder (e.g., an antibody, antigen binding fragment, and/or antibody domain) to an NE polypeptide. For example, binders (e.g., antibodies, antigen binding fragments, and/or antibody domains) that bind to an NE polypeptide and methods and materials for using one or more such binding molecules to treat a mammal (e.g., a human) having cancer and/or an inflammatory condition are provided.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2023/010453

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - INV. - A61K 39/395 (2023.01) ADD. - A61P 35/00; C07K 16/30 (2023.01) CPC - INV. - A61K 39/395; A61K 39/00116 (2023.05) ADD. - A61P 35/00; C07K 16/30; A61K 2039/505 (2023.05) 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 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	WO 2021/243169 A1 (VERSEAU THERAPEUTICS INC.) 02 December 2021 (02.12.2021) entire document	1-6, 9-12		
A	WO 2021/183195 A1 (ABCELLERA BIOLOGICS INC. et al.) 16 September 2021 (16.09.2021) entire document	1-6, 9-12		
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> * 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 </td> <td style="width: 50%; vertical-align: top;"> "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 </td> </tr> </table>			* 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
* 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 30 June 2023		Date of mailing of the international search report AUG 29 2023		
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300		Authorized officer Taina Matos Telephone No. PCT Helpdesk: 571-272-4300		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2023/010453

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.

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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.: 13, 14, 17-20, 23-41
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:

See extra sheet(s).

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.:
1-6, 9-12

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.

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 need to be paid.

Group I+: claims 1-12, 15, 16, 21, and 22 are drawn to antibodies, antigens, and antibody domains.

The first invention of Group I+ is restricted to an antibody comprising a heavy chain variable domain (VH) and a light chain variable domain (VL), where the VH is selected to be SEQ ID NO:8, which further contains HCDR1 (SEQ ID NO:1), HCDR2 (SEQ ID NO:2), HCDR3 (SEQ ID NO:3), and where the VL is selected to be SEQ ID NO:16, which further contains LCDR1 (SEQ ID NO:9), LCDR2 (SEQ ID NO:10), and LCDR3 (SEQ ID NO:11). It is believed that claims 1-3 read on this first named invention and thus these claims will be searched without fee to the extent that they read on SEQ ID NOS: 8 and 16.

Applicant is invited to elect additional antibody VH and VL, and their respective, corresponding, SEQ ID NOS to be searched in a specific combination by paying additional fee for each set of election. An exemplary election would be an antibody comprising a heavy chain variable domain (VH) and a light chain variable domain (VL), where the VH is selected to be SEQ ID NO:24, which further contains HCDR1 (SEQ ID NO:17), HCDR2 (SEQ ID NO:18), HCDR3 (SEQ ID NO:19), and where the VL is selected to be SEQ ID NO:16, which further contains LCDR1 (SEQ ID NO:9), LCDR2 (SEQ ID NO:10), and LCDR3 (SEQ ID NO:11). Additional antibody VH and VL, and their respective, corresponding, SEQ ID NOS will be searched upon the payment of additional fees. Applicants must specify the claims that read on any additional elected inventions. Applicants must further indicate, if applicable, the claims which read on 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.

The inventions listed in Groups I+ 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 Groups I+ formulas do not share a significant structural element, requiring the selection of alternative antibody VH and VL where "a heavy chain variable domain or region comprising the amino acid sequences set forth in SEQ ID NO: 1 (or SEQ ID NO: 1 with one, two, or three amino acid additions, deletions, or substitutions), SEQ ID NO:2 (or SEQ ID NO:2 with one, two, or three amino acid additions, deletions, or substitutions), and SEQ ID NO:3 (or SEQ ID NO:3 with one, two, or three amino acid additions, deletions, or substitutions), and a light chain variable domain or region comprising the amino acid sequences set forth in SEQ ID NO:9 (or SEQ ID NO:9 with one, two, or three amino acid additions, deletions, or substitutions), SEQ ID NO: 10 (or SEQ ID NO: 10 with one, two, or three amino acid additions, deletions, or substitutions), and SEQ ID NO:11 (or SEQ ID NO:11 with one, two, or three amino acid additions, deletions, or substitutions); or (ii) a heavy chain variable domain or region comprising the amino acid sequences set forth in SEQ ID NO: 17 (or SEQ ID NO: 17 with one, two, or three amino acid additions, deletions, or substitutions), SEQ ID NO: 18 (or SEQ ID NO: 18 with one, two, or three amino acid additions, deletions, or substitutions), and SEQ ID NO: 19 (or SEQ ID NO: 19 with one, two, or three amino acid additions, deletions, or substitutions)."

Additionally, even if Groups I+ were considered to share the technical features of an antibody comprising a heavy chain variable domain or region; an antigen binding fragment comprising a heavy chain variable domain or region; and an antibody domain comprising a heavy chain variable domain or region, these shared technical features do not represent a contribution over the prior art.

Specifically, WO 2021/243169 A1 to Verseau Therapeutics, Inc. (hereinafter, "Versseau") teaches a heavy chain variable domain or region (Claim 1, antibody, or antigen-binding fragment thereof; Claim 4, monoclonal antibody, or antigen-binding fragment thereof, of any one of claims 1-3, wherein the monoclonal antibody, or antigen-binding fragment thereof, comprises: a) a heavy chain sequence with at least about 90% identity to a heavy chain sequence selected from the group consisting of the heavy chain sequences listed in Table 2); an antigen binding fragment comprising a heavy chain variable domain or region (Claim 1, antibody, or antigen-binding fragment thereof; Claim 4, monoclonal antibody, or antigen-binding fragment thereof, of any one of claims 1-3, wherein the monoclonal antibody, or antigen-binding fragment thereof, comprises: a) a heavy chain sequence with at least about 90% identity to a heavy chain sequence selected from the group consisting of the heavy chain sequences listed in Table 2); and an antibody domain comprising a heavy chain variable domain or region (Claim 1, antibody, or antigen-binding fragment thereof; Claim 4, monoclonal antibody, or antigen-binding fragment thereof, of any one of claims 1-3, wherein the monoclonal antibody, or antigen-binding fragment thereof, comprises: a) a heavy chain sequence with at least about 90% identity to a heavy chain sequence selected from the group consisting of the heavy chain sequences listed in Table 2).

The inventions listed in Groups I+ therefore lack unity under Rule 13 because they do not share a same or corresponding special technical features.