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(71) Applicant: GENENTECH, INC. [US/US]; 1 DNA Way, South San Francisco, California 94080-4990 (US).

(72) Inventors: HUI, Ada; c/o Genentech, Inc., 1 DNA Way, South San Francisco, California 94080-4990 (US). ZHU-SHIMONI, Judith; c/o Genentech, Inc., 1 DNA Way, South San Francisco, California 94080-4990 (US).

(74) Agent: BANKO, Max et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, California 94304-1018 (US).

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Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

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— 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))

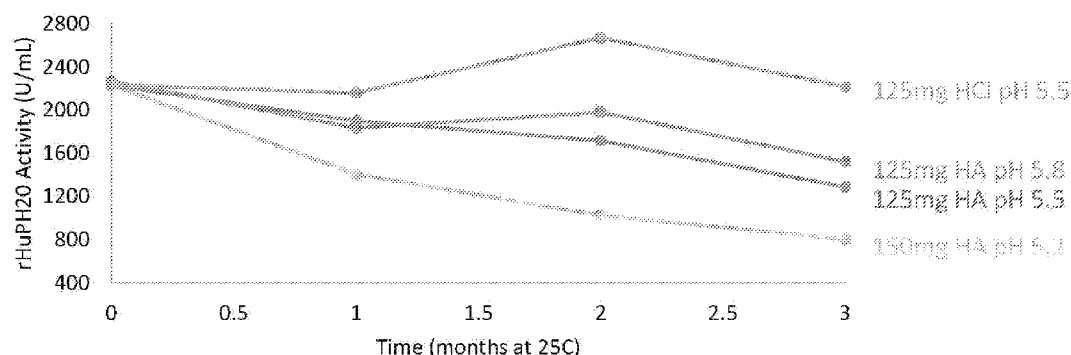
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19 August 2021 (19.08.2021)

(54) Title: ANTI-PD-L1 ANTIBODY FORMULATIONS

FIG. 9B

rHuPH20 Activity at 25°C



(57) Abstract: The invention provides liquid pharmaceutical formulations comprising an anti-PD-L1 antibody, such as liquid pharmaceutical formulations for subcutaneous administration. The invention also provides methods for making such formulations and methods of using such formulations.



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/063620

A. CLASSIFICATION OF SUBJECT MATTER
INV. C07K16/28 A61P35/00 A61K39/395
ADD.

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)
C07K A61P A61K

Documentation searched other than minimum documentation to 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)

EPO-Internal, BIOSIS, CHEM ABS Data, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/048520 A1 (GENENTECH INC [US]; HOFFMANN LA ROCHE [CH]) 2 April 2015 (2015-04-02)	17-28, 31-53
Y	examples, claims	1-16,29, 30,54,55
Y	SUMIT GOSWAMI ET AL: "Developments and Challenges for mAb-Based Therapeutics", ANTIBODIES, vol. 2, no. 3, 16 August 2013 (2013-08-16) , pages 452-500, XP055128980, DOI: 10.3390/antib2030452 pages 460-461	1-16, 31-55
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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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search

9 July 2021

Date of mailing of the international search report

20/07/2021

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Bernhardt, Wiebke

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2020/063620

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	LAM X M ET AL: "ANTIOXIDANTS FOR PREVENTION OF METHIONINE OXIDATION IN RECOMBINANT MONOCLONAL ANTIBODY HER2", JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN CHEMICAL SOCIETY AND AMERICAN PHARMACEUTICAL ASSOCIATION, US, vol. 86, no. 11, 1 November 1997 (1997-11-01), pages 1250-1255, XP008038003, ISSN: 0022-3549, DOI: 10.1021/JS970143S abstract, table 1	1-16, 31-55
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Y	----- WO 2018/136412 A2 (GENENTECH INC [US]; HOFFMANN LA ROCHE [CH]) 26 July 2018 (2018-07-26) pages 42-43, claims	1-55
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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	AKINLEYE AKINTUNDE ET AL: "Immune checkpoint inhibitors of PD-L1 as cancer therapeutics", JOURNAL OF HEMATOLOGY & ONCOLOGY, vol. 12, no. 1, 5 September 2019 (2019-09-05), XP055785954, DOI: 10.1186/s13045-019-0779-5 abstract, pages 4-6, tables 1-3 -----	1-55
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2020/063620

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:
- ☒ 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 13~~ter~~.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 13~~ter~~.1(a)).
- ☐ on paper or in the form of an image file (Rule 13~~ter~~.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

International application No.
PCT/US2020/063620

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:

see additional sheet

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 an 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.:

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16(completely); 31-55(partially)

A liquid pharmaceutical formulation, the formulation comprising a monoclonal anti-PD-L1 antibody comprising the 6 CDRs with Seq ID No. 1-6 in a concentration of about 100 g/L to about 150 g/L, histidine acetate in a concentration of about 15 mM to about 25 mM, sucrose in a concentration of about 200 mM to about 280 mM, polysorbate in a concentration of about 0.04% (w/v) to about 0.08% (w/v), methionine in a concentration of about 5 mM to about 15 mM, and pH of about 5.6 to about 6.0; an article of manufacture comprising said liquid formulations; a kit comprising said liquid formulations; medical use of said liquid formulations

2. claims: 17-30(completely); 31-55(partially)

A liquid pharmaceutical formulation, the formulation comprising a monoclonal anti-PD-L1 antibody comprising the 6 CDRs with Seq ID No. 1-6 in a concentration of about 100 g/L to about 150 g/L, histidine acetate in a concentration of about 15 mM to about 25 mM, sucrose in a concentration of about 200 mM to about 280 mM, polysorbate in a concentration of about 0.01% (w/v) to about 0.03% (w/v), and pH of about 5.3 to about 5.7; an article of manufacture comprising said liquid formulations; a kit comprising said liquid formulations; medical use of said liquid formulations

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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