(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 January 2017 (19.01.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/011580 A3

(51) International Patent Classification:
C07K 16/28 (2006.01) *A61K 39/00* (2006.01)
A61K 39/395 (2006.01)

(21) International Application Number:
PCT/US2016/042141

(22) International Filing Date:
13 July 2016 (13.07.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/191,902	13 July 2015 (13.07.2015)	US
62/205,825	17 August 2015 (17.08.2015)	US
62/295,314	15 February 2016 (15.02.2016)	US
62/323,543	15 April 2016 (15.04.2016)	US
62/333,629	9 May 2016 (09.05.2016)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

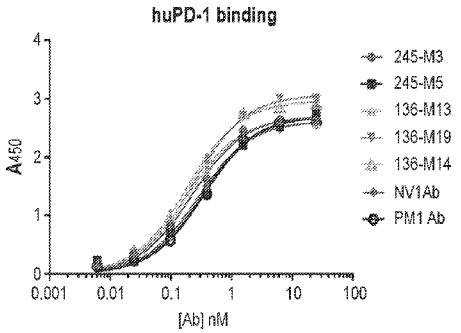
— *with international search report (Art. 21(3))*

— *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))*

(88) Date of publication of the international search report:
30 March 2017

(54) Title: ANTI-PD-1 ANTIBODIES, ACTIVATABLE ANTI-PD-1 ANTIBODIES, AND METHODS OF USE THEREOF

FIGURE 1



(57) Abstract: The invention relates generally to antibodies that specifically bind programmed cell death protein 1 (PD-1), activatable antibodies that specifically bind to PD-1 and methods of making and using these anti-PD-1 antibodies and anti-PD-1 activatable antibodies in a variety of therapeutic, diagnostic and prophylactic indications.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/042141

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

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 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, 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.
Y	WO 2006/121168 A1 (ONO PHARMACEUTICAL CO [JP]; MEDAREX INC [US]; KORMAN ALAN J; SRINIVASA) 16 November 2006 (2006-11-16) page 80; table 2 examples 4, 6, 13-20	2,30, 32-62
Y	US 8 735 553 B1 (LI KANG [CN] ET AL) 27 May 2014 (2014-05-27) column 29, line 32 - line 36 examples 7, 12	2,30, 32-62
Y	WO 2008/156712 A1 (ORGANON NV [NL]; CARVEN GREGORY JOHN [US]; VAN EENENNAAM HANS [NL]; DU) 24 December 2008 (2008-12-24) page 47, paragraph 3 page 48, paragraph 2 sequences 31, 36	2,30, 32-62

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[X] Further documents are listed in the continuation of Box C.

[X] 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

"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	Date of mailing of the international search report
8 February 2017	17/02/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Malamoussi, A

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Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	WO 2014/179664 A2 (ANAPTYSBIO INC [US]) 6 November 2014 (2014-11-06) page 37; table 1 page 37, paragraph 0111	2,30, 32-62
Y	US 2013/309250 A1 (COGSWELL JOHN [US] ET AL) 21 November 2013 (2013-11-21) page 7, paragraph 0062 - paragraph 0064	2,30, 32-62
Y	KRISHNA R POLU ET AL: "Probody therapeutics for targeting antibodies to diseased tissue", EXPERT OPINION ON BIOLOGICAL THERAPY, vol. 14, no. 8, 1 August 2014 (2014-08-01) , pages 1049-1053, XP055228738, ASHLEY, LONDON; GB ISSN: 1471-2598, DOI: 10.1517/14712598.2014.920814 title page 1049, paragraph 1 figure 1B page 1052, right-hand column, paragraph 3	2,30, 32-62
Y	JOSHUA M. DONALDSON ET AL: "Design and development of masked therapeutic antibodies to limit off-target effects: Application to anti-EGFR antibodies", CANCER BIOLOGY & THERAPY, vol. 8, no. 22, 15 November 2009 (2009-11-15), XP055274198, US ISSN: 1538-4047, DOI: 10.4161/cbt.8.22.9765 abstract page 2145, right-hand column, paragraph 1	2,30, 32-62
Y	Ulrich H Weidle ET AL: "Proteases as activators for cytotoxic prodrugs in antitumor therapy", Cancer genomics & proteomics, 1 March 2014 (2014-03-01), page 67, XP055263152, Greece Retrieved from the Internet: URL:http://cgp.iiarjournals.org/content/11/2/67.full.pdf [retrieved on 2016-04-06] page 74 - page 75 page 74, right-hand column, paragraph 3 page 75, left-hand column, paragraph 1	2,30, 32-62

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2010/081173 A2 (CYTOMX THERAPEUTICS LLC [US]; STAGLIANO NANCY E [US]; WEST JAMES W [US]) 15 July 2010 (2010-07-15) page 6, paragraph 0049 - paragraph 0050 figure 4 -----	2,30, 32-62
A	MEI GUAN ET AL: "Adverse Events of Monoclonal Antibodies Used for Cancer Therapy", BIOMED RESEARCH INTERNATIONAL, vol. 21, no. 1, 1 January 2015 (2015-01-01), pages 80-13, XP055320217, US ISSN: 2314-6133, DOI: 10.1158/1078-0432.CCR-12-2982 the whole document -----	2,30, 32-62
X,P	Kimberly A Tipton ET AL: "PD-1 ProbodyTM Therapeutic Anti-tumor Efficacy and Protection Against Autoimmunity in Preclinical Models", , 1 June 2016 (2016-06-01), pages 1-1, XP055321405, Retrieved from the Internet: URL:http://cytomx.com/wp-content/uploads/2016/04/PD-1-ProbodyTM-Therapeutic-Anti-tumor-Efficacy-and-Protection-Against-Autoimmunity-in-Preclinical-Models-AACR-2016.pdf [retrieved on 2016-11-21]	2,36,44
Y,P	the whole document -----	30, 32-35, 37-43, 45-62
A,P	Anonymous: "/PD-1-ProbodyTM-Therapeutic-An BROWSE HISTORY http://cytomx.com/wp-content/uploads/2016/04/PD-1-ProbodyTM-Therapeutic-Anti-tumor-Efficacy-and-Protection-Against-Autoimmunity-in-Preclinical-Models-AACR-2016.pdf/PD-1-ProbodyTM-Therapeutic-Anti-tumor-Efficacy-and-Protection-Against-Autoimmunity-in-P", , 21 November 2016 (2016-11-21), XP055321428, Retrieved from the Internet: URL:https://archive.org/ [retrieved on 2016-11-21] the whole document ----- -/--	2,30, 32-62

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Anonymous: "International Nonproprietary Names for Pharmaceutical Substances (INN) RECOMMENDED International Nonproprietary Names: List 72 Notice is hereby given that, in accordance with paragraph 7 of the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substance", WHO Drug Information Rec. Wld Health Org.Resolution EB15.R7), 1 January 2014 (2014-01-01), pages 379-422, XP055320420, Retrieved from the Internet: URL:http://www.who.int/entity/medicines/publications/druginformation/innlists/RL72.pdf?ua=1 [retrieved on 2016-11-17] page 407 -----	2,30, 32-62

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/042141

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/US2016/042141

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.: 1, 3-29, 73-101
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:

see FURTHER INFORMATION sheet PCT/ISA/210

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.:

2, 30, 34(completely); 32, 33, 35-62(partially)

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: 2, 30, 34(completely); 32, 33, 35-62(partially)

relating to an activatable antibody wherein the AB comprises a VH CDR1 sequence comprising GFTFSGYAMS (SEQ ID NO: 653); a VH CDR2 sequence comprising YISNSGGNAH (SEQ ID NO: 658); a VH CDR3 sequence comprising EDYGTSPFVY (SEQ ID NO: 664); a VL CDR1 sequence comprising RASESVDAYGISFMN (SEQ ID NO: 676); a VL CDR2 sequence comprising AASNQGS (SEQ ID NO: 678); and a VL CDR3 sequence comprising QQSKDVPWT (SEQ ID NO: 683).

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2. claims: 31(completely); 32, 33, 35-62(partially)

relating to an activatable antibody wherein the AB comprises a VH CDR1 sequence comprising GFTFSGYAMS (SEQ ID NO: 653); a VH CDR2 sequence comprising YISNSGGNAH (SEQ ID NO: 658); a VH CDR3 sequence comprising EDYGTSPFVY (SEQ ID NO: 664); a VL CDR1 sequence comprising RASESVDSYGISFMN (SEQ ID NO: 675); a VL CDR2 sequence comprising AASNQGS (SEQ ID NO: 678); and a VL CDR3 sequence comprising QQSKDVPWT (SEQ ID NO: 683)

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3. claims: 63-67

relating to an activatable antibody wherein the AB comprises (i) a combination of the complementarity determining region (CDR) sequences of the heavy chain amino acid sequence of SEQ ID NO: 1346 and the CDR sequences of the light chain amino acid sequence of SEQ ID NO: 626 or (ii) a combination of a VH CDR1 sequence, a VH CDR2 sequence, a VH CDR3 sequence, a VL CDR1 sequence, a VL CDR2 sequence, and a VL CDR3 sequence, wherein the VH CDR1 sequence comprises GITFSNSG (SEQ ID NO: 1705); the VH CDR2 sequence comprises IWYDGSKR (SEQ ID NO: 1706); the VH CDR3 sequence comprises TNDDY (SEQ ID NO: 1707); the VL CDR1 sequence comprises QSVSSY (SEQ ID NO: 1708); the VL CDR2 sequence comprises DAS (SEQ ID NO: 1709); and the VL CDR3 sequence comprises QQSSNWPRT (SEQ ID NO: 1710).

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4. claims: 68-72

The activatable antibody of any one of claims 2 to 28 and 35 to 56, wherein the AB comprises:(i) a combination of the complementarity determining region (CDR) sequences of the heavy chain amino acid sequence of SEQ ID NO: 1514 and the CDR sequences of the light chain amino acid sequence of SEQ ID NO: 638 or (ii) a combination of a VH CDR1 sequence, a VH CDR2 sequence, a VH CDR3 sequence, a VL CDR1 sequence, a VL CDR2 sequence, and a VL CDR3 sequence, wherein the VH CDR1

sequence comprises GYTFTNYY (SEQ ID NO: 1711); the VH CDR2 sequence comprises INPSNGGT (SEQ ID NO: 1712); the VH CDR3 sequence comprises RRDYRFDMGFDY (SEQ ID NO: 1713); the VL CDR1 sequence comprises KGVSTSGYSY (SEQ ID NO: 1714); the VL CDR2 sequence comprises LAS (SEQ ID NO: 1715); and the VL CDR3 sequence comprises QHSRDLPLT (SEQ ID NO: 1716).

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5. claims: 32, 33, 35-62(all partially)

any claimed antibody not covered by Inventions 1-4

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1, 3-29, 73-101

The present application comprises 101 claims relating to several thousand possible antibodies. According to Rule 6.1(a) PCT , the number of claims shall be reasonable in consideration of the nature of the invention claimed, which is not the case here.

The application relates to sequence combinations, which may or may not generate an antibody with defined technical properties. The examiner is unable to search the thousands of combinations claimed without undue burden.

For the purposes of an incomplete search, the applicant is requested to identify the subject matter to be searched in more detail, for example, with reference to fully defined antibodies disclose in the application and claims. The applicants comments will be considered when selecting the subject matter of the search, and for defining the subject matter of different inventions, should there be no common linking inventive concept found, in the sense of Rule 13 PCT.

In response, the applicant defined the subject matter of claim 2, as well as its dependent claims 30-72, for the purpose of search. Therefore, the search has been limited to the subject matter of claims 2 and 30-72.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/042141

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