

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P5073PC00	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2015/075628	International filing date (<i>day/month/year</i>) 3 November 2015 (03-11-2015)	(Earliest) Priority Date (<i>day/month/year</i>) 4 November 2014 (04-11-2014)
Applicant GLENMARK PHARMACEUTICALS S.A.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6**bis**(a)).

c. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☒ none of the figures is to be published with the abstract

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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:

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A. CLASSIFICATION OF SUBJECT MATTER
INV. C07K16/46 C07K16/28 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 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, WPI Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2011/154453 A1 (GENMAB AS [DK]; WEERS MICHEL DE [NL]; WALSETH TIM [US]; WINKEL JAN VAN) 15 December 2011 (2011-12-15) page 97 - page 107; examples 1-8 page 5 - page 10; sequences 1-50 page 73, paragraph 1	6-9
X	ELLIS JONATHAN H ET AL: "Engineered anti-CD38 monoclonal antibodies for immunotherapy of multiple myeloma", THE JOURNAL OF IMMUNOLOGY, THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS, US, vol. 155, no. 2, 1 January 1995 (1995-01-01), pages 925-937, XP002146232, ISSN: 0022-1767 abstract figure 3	1-5, 10-15
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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

"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

12 January 2016

Date of mailing of the international search report

29/01/2016

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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.
X	WO 2014/068114 A1 (MORPHOSYS AG [DE]) 8 May 2014 (2014-05-08) figure 1 sequences 1-6,14 abstract	1-5, 10-15
X	----- J. DECKERT ET AL: "SAR650984, A Novel Humanized CD38-Targeting Antibody, Demonstrates Potent Antitumor Activity in Models of Multiple Myeloma and Other CD38+ Hematologic Malignancies", CLINICAL CANCER RESEARCH, vol. 20, no. 17, 1 September 2014 (2014-09-01), pages 4574-4583, XP055239997, US ISSN: 1078-0432, DOI: 10.1158/1078-0432.CCR-14-0695	1-5, 10-12, 14,15
Y	abstract page 4578, left-hand column, paragraph 3 - right-hand column, paragraph 2	6-9
X	----- WO 2008/047242 A2 (SANOFI AVENTIS [FR]; PARK PETER U [US]; BARTLE LAURA M [US]; SKALETSKA) 24 April 2008 (2008-04-24)	1-5,10, 12-15
Y	page 4, line 1 - page 7, line 29 sequence 42 claims 52-56	6-9
X	----- M. DE WEERS ET AL: "Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors", THE JOURNAL OF IMMUNOLOGY, vol. 186, no. 3, 27 December 2010 (2010-12-27), pages 1840-1848, XP55210884, ISSN: 0022-1767, DOI: 10.4049/jimmunol.1003032 abstract	1-5, 10-15
X	----- WO 2012/092612 A1 (TAKEDA PHARMACEUTICAL [JP]; ELIAS KATHLEEN ANN [US]; LANDES GREGORY [U]) 5 July 2012 (2012-07-05) sequences 24-27 sequences 3-8 sequences 13-18 claims 1-19	1-5, 10-15
X,P	----- WO 2015/063339 A1 (GLENMARK PHARMACEUTICALS SA [CH]) 7 May 2015 (2015-05-07) pages 114-115 sequences 122-134 sequences 167-179	1-15
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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	EP 2 522 724 A1 (CHUGAI PHARMACEUTICAL CO LTD [JP]) 14 November 2012 (2012-11-14) paragraph [0012] paragraph [0014] paragraph [0075] paragraph [0015] paragraph [0016] paragraphs [0073] - [0074] figure 4; example 8 -----	1-15
A	WO 2012/131555 A2 (GLENMARK PHARMACEUTICALS SA [CH]; BLEIN STANISLAS [CH]; SKEGRO DARKO []) 4 October 2012 (2012-10-04) page 6, line 15 - page 11, line 16 -----	1-15
A	ROBEN P W ET AL: "VH3 family antibodies bind domain D of staphylococcal protein A", THE JOURNAL OF IMMUNOLOGY, THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS, US, vol. 154, no. 12, 15 June 1995 (1995-06-15), pages 6437-6445, XP002508063, ISSN: 0022-1767 abstract -----	1-15
A	POTTER K N ET AL: "Staphylococcal protein A binding to VH3 encoded immunoglobulins", INTERNATIONAL REVIEWS OF IMMUNOLOGY, HARWOOD ACADEMIC PUBLISHERS, LONDON, GB, vol. 14, no. 4, 1 January 1997 (1997-01-01), pages 291-308, XP008116757, ISSN: 0883-0185 abstract -----	1-15
A	GRAILLE M ET AL: "Crystal structure of a Staphylococcus aureus protein A domain complexed with the Fab fragment of a human IgM antibody: Structural basis for recognition of B-cell receptors and superantigen activity", PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF SCIENCES, US, vol. 97, no. 10, 9 May 2000 (2000-05-09), pages 5399-5404, XP002284947, ISSN: 0027-8424, DOI: 10.1073/PNAS.97.10.5399 abstract figure 1; table 1 ----- -/--	1-15

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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	ALMAGRO JUAN C ET AL: "Humanization of antibodies", FRONTIERS IN BIOSCIENCE, FRONTIERS IN BIOSCIENCE, ALBERTSON, NY, US, vol. 13, 1 January 2008 (2008-01-01), pages 1619-1633, XP009126790, ISSN: 1093-9946 p. 1624 right-hand col. 3rd paragraph - p. 1625 right-hand col. 2nd paragraph -----	1-15
A	WO 2010/151792 A1 (REGENERON PHARMA [US]; DAVIS SAMUEL [US]; SMITH ERIC [US]; MACDONALD D) 29 December 2010 (2010-12-29) paragraph [0024] paragraph [0025] paragraph [0026] paragraphs [0027] - [0028] paragraph [0165]; example 7 -----	1-15
A	WO 2014/049003 A1 (GLENMARK PHARMACEUTICALS SA [CH]) 3 April 2014 (2014-04-03) page 9, lines 1-13 page 11, line 27 - page 12, line 29 page 66, line 15 - page 69, line 33 claims 55-63, 67-69 -----	1-15
Y	LUM L G ET AL: "Development and prospects for bispecific antibody-based therapeutics in cancer and other applications", EXPERT OPINION ON DRUG DISCOVERY 200809 GB, vol. 3, no. 9, September 2008 (2008-09), pages 1081-1097, XP002752851, ISSN: 1746-0441 page 1088, left-hand column, paragraph 2 -----	6-9

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