

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PF0208-WO-PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2020/087046	International filing date (<i>day/month/year</i>) 18 December 2020 (18.12.2020)	Priority date (<i>day/month/year</i>) 20 December 2019 (20.12.2019)	
International Patent Classification (IPC) or national classification and IPC See relevant information in Form PCT/ISA/237			
Applicant UCB BIOPHARMA SRL			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).		
2.	This REPORT consists of a total of 7 sheets, including this cover sheet.		
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.		
3.	This report contains indications relating to the following items:		
	☒	Box No. I	Basis of the report
	☐	Box No. II	Priority
	☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
	☐	Box No. IV	Lack of unity of invention
	☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
	☐	Box No. VI	Certain documents cited
	☐	Box No. VII	Certain defects in the international application
	☐	Box No. VIII	Certain observations on the international application
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).		

	Date of issuance of this report 17 May 2022 (17.05.2022)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Nora Lindner e-mail pct.team5@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2020/087046

International filing date (day/month/year)
18.12.2020

Priority date (day/month/year)
20.12.2019

International Patent Classification (IPC) or both national classification and IPC
INV. C07K16/24 C07K16/18 A61P37/08 A61K39/395

Applicant
UCB BIOPHARMA SRL

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
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Tel. +31 70 340 - 2040
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established 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)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established 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 13ter.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 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ 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.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2020/087046

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-30</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-30</u>
Industrial applicability (IA)	Yes: Claims	<u>1-30</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty (Art. 33(2) PCT), inventive step (Art. 33(3) PCT) or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1 WO 2015/127405 A2 (GENENTECH INC [US]; HOFFMANN LA ROCHE [CH]) 27 August 2015 (2015-08-27)
- D2 WO 2013/102042 A2 (ABBVIE INC [US]) 4 July 2013 (2013-07-04)
- D3 WO 2012/095662 A1 (UCB PHARMA SA [BE]; ADAMS RALPH [GB] ET AL.) 19 July 2012 (2012-07-19)

The following independent claims are present on file:

1. A multi-specific antibody which binds human IL-13, human IL-17A and/or human IL-17F, comprising an IL-13 binding site which comprises:
a light chain variable region comprising the sequence given in SEQ ID NO:15 for CDR-L1, the sequence given in SEQ ID NO: 16 for CDR-L2 and the sequence given in SEQ ID NO:17 for CDR-L3, and
a heavy chain variable region comprising the sequence given in SEQ ID NO:18 for CDR-H1, the sequence given in SEQ ID NO: 19 for CDR-H2 and the sequence given in SEQ ID NO:20 for CDR-H3.
22. An isolated polynucleotide encoding a multi-specific antibody as defined in any one of claims 1 to 21.
23. An expression vector carrying the polynucleotide of claim 22.
24. A host cell comprising the vector as defined in claim 23.
25. A method of producing the multi-specific antibody as defined in any one of claims 1-21, comprising culturing the host cell of claim 24 under conditions permitting production of the antibody, and recovering the antibody produced.
27. A pharmaceutical composition comprising an antibody as defined in any one of claims 1 to 21 and a pharmaceutically acceptable adjuvant and/or carrier.

28. An antibody as defined in any one of claims 1-21 or a pharmaceutical composition as defined in claim 27 for use in a method of treatment of the human or animal body by therapy.

30. A method of treating or preventing atopic dermatitis, chronic hand eczema, nasal micropolypsis or polyposis, food allergy, or eosinophilic esophagitis, comprising administering a therapeutically effective amount of a multi-specific antibody according to claims 1-21 or a pharmaceutical composition according to claim 27 to a patient in need thereof.

In the worked examples, a single antibody clone (CA650) binding IL13 has been generated following immunisation of rats with human IL13; humanisation of the same was carried out. Production of a multipecific antibody based on this and an antibody binding IL17AF has been produced and studied, comparing such with for instance the multispecific antibodies known from D1 and D2.

1. **D1** discloses bispecific antibodies to IL13 and IL17 (binding AA, AF and FF);

D2 discloses dual variable domain binding proteins binding IL13 and/or IL17.

Claim 1 differs over either of these publication by nature of the 6 CDR sequences defining the IL-13 antibody aspect of the claim.

In the absence of a clear technical effect being able to be associated with this difference, the problem addressed is defined as how to provide further antibodies binding IL13.

The provision of further antibodies binding a known target, including as when such are defined by their complete CDR or VH/VL sequences, amounts to work of a routine nature in the art, and is therefore not inventive.

2. Given the lack of inventive step for the subject matter of claim 1, it follows that equally that of the remaining claims is not inventive, particularly in the absence of an ability to associate any specific, unexpected technical effect with the same.

3 It should be noted that patentability can be dependent upon the formulation of claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment. These comments may be applicable to present claim 30.