

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 792702000240		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 20/25469	International filing date (<i>day/month/year</i>) 27 March 2020 (27.03.2020)	(Earliest) Priority Date (<i>day/month/year</i>) 28 March 2019 (28.03.2019)	
Applicant AB STUDIO INC.			

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 5 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 43.6bis(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. 1

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 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).
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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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.: 4-43
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:
----Go to Extra Sheet for continuation-----

- 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.:
Claims 1-3

- 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.

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A. CLASSIFICATION OF SUBJECT MATTER

IPC - C07K 16/46; C07K 16/00 (2020.01)

CPC - C07K 16/46; C07K 16/468; C07K 2317/52; C07K 2317/526

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 data base consulted during the international search (name of data base 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.
X	CA 3031082 A1 (Ibentrus, Inc). 25 January 2018 (25.01.2018) abstract, pg 33 lln 13-14, pg 44 lln 15-24, pg 44 Table 3.	1-3
A	US 2012/0149876 A1 (Spreter Von Krudenstein et al.) 14 June 2012 (14.06.2012) para [0086], pg 7 Table A, claim 1.	1-3

 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

"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 2020

Date of mailing of the international search report

02 SEP 2020

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

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Continuation of Box 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 searched, the appropriate additional search fees must be paid.

Group I: Claims 1-3, drawn to a heteromultimeric protein composition.

Group II: Claim 44, drawn to a method of generating a heteromultimeric protein that specifically binds to a first target and a second target.

The inventions listed as Groups I and II 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:

Special Technical Features:

Group I has the special technical feature of a heteromultimeric protein comprising one or more amino acid substitutions relative to wild type, not required by Group II.

Group II has the special technical feature of a method of generating a heteromultimeric protein with specific steps involving amino acid substitutions in one or more amino acid positions in a first or second CH3 domain, not required by Group I.

Group II has the special technical feature of providing a first polypeptide comprising a first binding domain that specifically binds to a first target, and a second polypeptide comprising a second binding domain that specifically binds to a second target, not required by Group I.

Common Technical Features:

Groups I and II share the common technical features of:

1. A heteromultimeric protein comprising a first polypeptide comprising a first heavy chain constant domain 3 (CH3) domain and a second polypeptide comprising a second CH3 domain.
2. the first CH3 domain comprises a substitution relative to a wildtype CH3 domain at amino acid position 354 with a bulky hydrophobic amino acid.

However, said common technical features do not represent a contribution over the prior art and is disclosed by WO 2018/016881 A1 to Ibtentrus Co., Ltd. (hereinafter "Ibtentrus") [Google Korean to English translation provided].

As to common technical feature #1, Ibtentrus discloses a heteromultimeric protein comprising a first polypeptide comprising a first heavy chain constant domain 3 (CH3) domain and a second polypeptide comprising a second CH3 domain (abstract; "a bispecific protein with a purity of heterodimers which is prepared by introducing a mutation into a heavy chain and/or a light chain to thus increase a heterodimer formation rate between a heavy chain (CH3 domain or Fc) and a heavy chain (CH3 domain or Fc)").

As to common technical feature #2, Ibtentrus discloses the first CH3 domain comprises a substitution relative to a wildtype CH3 domain at amino acid position 354 with a bulky hydrophobic amino acid (PDF pg 27 Example 1; "For the associated i mutation by swapping the A chain and the amino acid of the B chain was changed to each other. In the case of associated mutations by size, the A chain is the W (tryptophan), B chain is the size Replaced with a small A (alanine)"; PDF pg 27 Table 3: Amino Acid Pair No: 7; Swap: Chain 1: S354Y Chain 2: Y349S or Size: Chain 1: S354W Y349A).

As the common technical features were known in the art at the time of the invention, they cannot be considered common special technical features that would otherwise unify the groups. The inventions lack unity with one another.

Therefore, Groups I and II lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Item 4 (cont.): Claims 4-43 are multiple dependent claims and are not drafted according to the second and third sentences of PCT Rule 6.4(a).