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(54) Title: MONOCLONAL ANTIBODIES AGAINST JC VIRUS

(57) Abstract: Provided herein are monoclonal antibodies and antigen-binding fragments thereof that bind to the John Cunningham virus. Also provided are pharmaceutical compositions comprising the monoclonal antibodies and antigen-binding fragments thereof, as well as methods of using such monoclonal antibodies and antigen-binding fragments thereof, including methods for the treatment and/or prevention of JCV infections and/or progressive multifocal leukoencephalopathy.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/38708

A. CLASSIFICATION OF SUBJECT MATTER

IPC - C07K 16/08; A61K 39/395; A61K 39/42; A61P 25/28 (2020.01)

CPC - C07K 16/084; A61K 2039/505; C07K 2317/56; C07K 2317/565; C07K 2317/24

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.
A	US 9,567,391 B2 (BIOGEN IDEC MA) 14 February 2017 (14.02.2017). Especially col 1 ln 30-34, claim 1	1-4, 58/(1-4)
A	US 2011/0263827 A1 (GHAYUR et al.) 27 October 2011 (27.10.2011). Especially para [0019] SEQ ID NO: 33	1-4, 58/(1-4)
A	US 2010/0008851 A1 (NICOLAIDES) 14 January 2010 (14.10.2010). Especially para [0010] SEQ ID NO: 42	1-4, 58/(1-4)

☐ 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

24 September 2020

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/38708

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:

GenCore ver 6.4.1 SEQ ID NOs 5, 12, 23, 36, KVS, 45, 101 and 102.were searched .

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/38708

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.: 59-66, 68-115
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 1-4, 58, limited to SEQ ID NOS: 5, 12, 23, 36, KVS, 45, 101 and 102.

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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US 20/38708

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 1-58, drawn to an antibody that binds to the John Cunningham virus (JCV), the antibody comprising a heavy chain variable region and a light chain variable region.

The antibody will be searched to the extent that the CDRH1, CDRH2, CDRH3, CDRL1, CDRL2, CDRL3 are the first named, SEQ ID NOs: 5, 12, 23, 36, KVS and 45, respectively (claim 2), which are comprised by VH SEQ ID NO: 101 and VL SEQ ID NO: 102. It is believed that claims 1-4, 58 read on this first named invention and thus these claims will be searched without fee to the extent that they encompass SEQ ID NOs: 5, 12, 23, 36, KVS, 45, 101 and 102. Additional antibody heavy chain variable region and light chain variable regions and their respective CDR-1,2,3s will be searched upon payment of additional fees. Applicant must specify the claims that encompass any additional elected CDRs or VH or VL. Applicants must further indicate, if applicable, the claims which read on the first named invention if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "*" group(s) will result in only the first claimed invention to be searched/examined. An exemplary election would be: CDRH1, CDRH2, CDRH3, CDRL1, CDRL2, CDRL3 SEQ ID NOs: 6, 16, 29, 39, WAS, 48, respectively, comprised by VH SEQ ID NO: 85 and VL SEQ ID NO: 86 (claims 31-34, 58).

Group II: Claim 67, drawn to an isolated nucleic acid sequence.

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:

Technical Features:

Group I+ has the special technical feature of an antibody that binds to the John Cunningham virus (JCV), the antibody comprising a heavy chain variable region and a light chain variable region, not required by Group II.

Group II has the special technical feature of an isolated nucleic acid sequence, not required by Group I+.

No technical features are shared between the polypeptide sequences of Group I+, and, accordingly, this group lacks unity a priori.

Additionally, even if Groups I+ Inventions and Group II were considered to share the technical features of:

1. an antibody that binds to the John Cunningham virus (JCV), the antibody comprising a heavy chain variable region and a light chain variable region, wherein each of the heavy chain and light chain regions comprise CDR1, CDR2, CDR3.

said shared technical features do not represent a contribution over the prior art, and are disclosed by US 9,567,391 B2 to Biogen Idec MA, Inc. (hereinafter "Biogen").

As to common technical features #1, Biogen discloses an antibody that binds to the John Cunningham virus (JCV), the antibody comprising a heavy chain variable region and a light chain variable region, wherein each of the heavy chain and light chain regions comprise CDR1, CDR2, CDR3 (claim 1; "1. An isolated monoclonal antibody comprising: a heavy chain variable domain comprising a CDR1 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:48, a CDR2 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:49, and a CDR3 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:63; and a light chain variable domain comprising a CDR1 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:64, a CDR2 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:65, and a CDR3 amino acid sequence that is identical to the amino acid sequence of SEQ ID NO:66"; col 1 in 30-34; "In some embodiments, aspects of the invention relate to an isolated JC-virus neutralizing monoclonal antibody against JCV capsid protein VP1 (JCV-VP1). In some embodiments, the antibody suppresses infectivity of the JC-virus").

As the shared technical features were known in the art at the time of the invention, they cannot be considered shared 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 59-66, 68-115 are held unsearchable because they are not drafted according to the second and third sentences of PCT Rule 6.4(a).