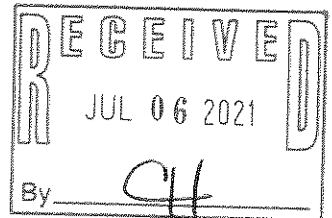


PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY



PCT

To: CHRISTOPHER L. CURFMAN
MEUNIER CARLIN & CURFMAN LLC
999 PEACHTREE ST. NE
SUITE 1300
ATLANTA, GA 30309

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 10029-076WO1	Date of mailing (day/month/year) JUN 28 2021 FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2021/016984	International filing date (day/month/year) 07 February 2021
Applicant EMORY UNIVERSITY	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland
(Facsimile No.: +41 22 338 82 70)

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45bis.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Harry Kim Telephone No. PCT Helpdesk: 571-272-4300
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 10029-076WO1		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2021/016984	International filing date (day/month/year) 07 February 2021	(Earliest) Priority Date (day/month/year) 07 February 2020	
Applicant EMORY UNIVERSITY			

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/016984

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.: 42-46, 57, 58, 73, 76, 77
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 extra sheet(s).

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.:
1st invention: claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, 75
2nd invention: claims 1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74
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.:

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

International application No.

PCT/US2021/016984

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.01)
 CPC - A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.05)

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	1st invention: US 2019/0083520 A1 (EMORY UNIVERSITY) 21 March 2019 (21.03.2019) entire document	1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, 75
X	2nd invention: WO 2019/113462 A1 (EMORY UNIVERSITY) 13 June 2019 (13.06.2019) entire document	1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74
A	US 2019/0083520 A1 (EMORY UNIVERSITY) 21 March 2019 (21.03.2019) entire document	1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74

☐ 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

19 May 2021

Date of mailing of the international search report

JUN 28 2021

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Harry Kim

Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/016984

Continued from Box No. III Observations where unity of invention is lacking

Claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, and 75 have been analyzed subject to the restriction that the claims read on a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is H.

Claims 1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, and 74 (as best interpreted) have been analyzed subject to the restriction that the claims read on the Formula XXI as described in the Response to the Invitation to Pay Additional Fees in the International Application dated 05 May 2021 as further restricted to the variable definitions listed below. The claims are restricted to a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is R6C(O), where R6 is alkyl.

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 examined, the appropriate additional examination fees need to be paid.

Group I+: claims 1-41, 47-56, 59-72, 74, and 75 are drawn to pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection.

The first invention of Group I+ is restricted to a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is H; pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection. It is believed that claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, and 75 read on this first named invention and thus these claims will be searched without fee to the extent that they read on the above embodiment.

Applicant is invited to elect additional formula(e) for each additional compound to be searched in a specific combination by paying an additional fee for each set of election. Each additional elected formula(e) requires the selection of a single definition for each compound variable. An exemplary election would be a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is the first shown mono-phosphate moiety; pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection. Additional formula(e) will be searched upon the payment of additional fees. Applicants must specify the claims that read on any additional elected inventions. 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.

The inventions listed in Groups I+ 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:

The Groups I+ formulae do not share a significant structural element requiring the selection of alternatives for the compound variables, R1, R2, R3, R5, X, Y, Z, and accordingly these groups lack unity a priori.

Additionally, even if Groups I+ were considered to share the technical features of a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection; COVID-19, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, and a compound having the core structure of Formula I, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof; a method of treating 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof, comprising administering an effective amount of a compound with the structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, to the patient; a method of preventing 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof, comprising administering an effective amount of a compound with the structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, to the patient; a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, comprising a pharmaceutically acceptable excipient and a compound with the following structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof; and one or more antiviral agent; a method of treating a 2019nCoV/SARS-CoV-2 infection, and COVID-19, comprising administering an effective amount of a compound with the following structure shown: or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, and one or more antiviral agent, these shared technical features do not represent a contribution over the prior art as disclosed by US 2019/0083520 A1 to Emory University.

US 2019/0083520 A1 to Emory University teaches a pharmaceutical composition (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I) for the treatment of 2019nCoV/SARS-CoV-2 infection (Para. [0305], in some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus; i.e., The present invention is useful for treating a wide range of coronavirus variants which inherently includes 2019nCoV/SARS-CoV-2 and COVID-19); COVID-19 (Para. [0305]), comprising a pharmaceutically acceptable excipient (Para. [0308], a pharmaceutical compositions comprises a pharmaceutically acceptable excipient, such as a pharmaceutically acceptable carrier; Claim 1) and a compound of Formula XXI (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and a compound having the core structure of Formula I (Claim 16, see shown structure); a method of treating 2019nCoV/SARS-CoV-2 virus infection and COVID-19 in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); a method of preventing 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19 (Claim 1, Para. [0305]), comprising a pharmaceutically acceptable excipient (Para. [0308] and a compound with the following structure shown (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); and one or more antiviral agent selected from abacavir (Para. [0352], in combination with another antiviral agent(s) such as abacavir); a method of treating a 2019nCoV /SARS-CoV-2 infection, and COVID-19 (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and one or more antiviral agent selected from abacavir (Para. [0352], in combination with another antiviral agent(s) such as abacavir).

The inventions listed in Groups I+ therefore lack unity under Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: CHRISTOPHER L. CURFMAN
MEUNIER CARLIN & CURFMAN LLC
999 PEACHTREE ST. NE
SUITE 1300
ATLANTA, GA 30309

Date of mailing
(day/month/year)

JUN 28 2021

Applicant's or agent's file reference
10029-076WO1

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2021/016984

International filing date (day/month/year)

07 February 2021

Priority date (day/month/year)

07 February 2020

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.01)

CPC - A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.05)

Applicant **EMORY UNIVERSITY**

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 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/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

19 May 2021

Authorized officer

Harry Kim

PCT Helpdesk: 571-272-4300
Telephone No. 571-272-4300

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2021/016984

Box No. I Basis of this 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(b)).

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/US2021/016984

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 42-46, 57, 58, 73, 76, 77

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 42-46, 57, 58, 73, 76, 77 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 42-46, 57, 58, 73, 76, and 77 are multiple dependent claims not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 42-46, 57, 58, 73, 76, 77

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2021/016984

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:

<See Supplemental Box>

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. see each elected species below

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2021/016984

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

1. Statement

Novelty (N)	Claims	see each elected species below	YES
	Claims	see each elected species below	NO
Inventive step (IS)	Claims	see each elected species below	YES
	Claims	see each elected species below	NO
Industrial applicability (IA)	Claims	see each elected species below	YES
	Claims	see each elected species below	NO

2. Citations and explanations:

1st Invention

Novelty (N)	Claims	47, 67, 69, 75	YES
	Claims	1, 2, 4, 8-10, 51, 55, 59, 60, 63, 64	NO
Inventive step (IS)	Claims	None	YES
	Claims	1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, 75	NO
Industrial applicability (IA)	Claims	1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, 75	YES
	Claims	None	NO

Claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, and 75 have been analyzed subject to the restriction that the claims read on a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is H.

Claims 1, 2, 4, 8-10, 51, 55, 59, 60, 63, and 64 lack novelty under PCT Article 33(2) as being anticipated by US 2019/0083520 to Emory University (hereinafter, "Emory '520").

Regarding Claim 1, Emory '520 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I; Paras. [0305]-[0306]. In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV), comprising a pharmaceutically acceptable excipient (Para. [0308], a pharmaceutical compositions comprises a pharmaceutically acceptable excipient, such as a pharmaceutically acceptable carrier; Claim 1) and a compound of Formula XXI, wherein R1 is H (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931). In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 2, Emory '520 discloses the pharmaceutical composition of claim 1, wherein the compound has the following structure shown (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Regarding Claim 4, Emory '520 discloses a pharmaceutical composition for the treatment of COVID (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I; Paras. [0305]-[0306]. In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV), comprising a pharmaceutically acceptable excipient (Para. [0308]) and a compound with the following structure shown (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931). In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 8, Emory '520 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claim 1, Paras. [0305]-[0306]), comprising a pharmaceutically acceptable excipient (Para. [0308]) and a compound of Formula I, wherein X is CH₂; Y is CR; Z is CR; R' is hydrogen; R" is hydrogen; R1, R2, R3, and R5 are each independently H (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931). In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1, 3, 5, 6, 8, 11, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s):

Regarding claims 1, 3, 5, 6, 8, 11, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74, in the Response to the Invitation to Pay Additional Fees in the International Application dated 05 May 2021, the specific claims that read on the additional elected invention listed as claims 1, 3, 5, 6, 8, 11, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74, are improper. Claims 6 and 11 do not read on the additionally selected invention. For the purposes of this Written Opinion proposed, claims 6 and 11 are not searched. The applicant did not select a single definition for each compound variable, specifically for each instance of variable R6 which is defined as "where R6 is alkyl or carbocyclyl". For the purposes of this Written Opinion proposed, R6 is defined as alkyl, as best interpreted.

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Supplemental Box

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Continuation of:

<Box No. IV Lack of unity of invention>

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 examined, the appropriate additional examination fees need to be paid.

Group I+: claims 1-41, 47-56, 59-72, 74, and 75 are drawn to pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection.

The first invention of Group I+ is restricted to a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is H; pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection. It is believed that claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, and 75 read on this first named invention and thus these claims will be searched without fee to the extent that they read on the above embodiment.

Applicant is invited to elect additional formula(e) for each additional compound to be searched in a specific combination by paying an additional fee for each set of election. Each additional elected formula(e) requires the selection of a single definition for each compound variable. An exemplary election would be a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is the first shown mono-phosphate moiety; pharmaceutical compositions for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, and methods of treating 2019nCoV/SARS-CoV-2 virus infection, COVID, and COVID-19, and methods of treating or preventing infections caused by 2019nCoV/SARS-CoV-2 infection. Additional formula(e) will be searched upon the payment of additional fees. Applicants must specify the claims that read on any additional elected inventions. 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.

The inventions listed in Groups I+ 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:

The Groups I+ formulae do not share a significant structural element requiring the selection of alternatives for the compound variables, R1, R2, R3, R5, X, Y, Z, and accordingly these groups lack unity a priori.

Additionally, even if Groups I+ were considered to share the technical features of a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection; COVID-19, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, and a compound having the core structure of Formula I, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof; a method of treating 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof, comprising administering an effective amount of a compound with the structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, to the patient; a method of preventing 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof, comprising administering an effective amount of a compound with the structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, to the patient; a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19, comprising a pharmaceutically acceptable excipient and a compound with the following structure shown or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof; and one or more antiviral agent; a method of treating a 2019nCoV/SARS-CoV-2 infection, and COVID-19, comprising administering an effective amount of a compound with the following structure shown: or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, and one or more antiviral agent, these shared technical features do not represent a contribution over the prior art as disclosed by US 2019/0083520 A1 to Emory University.

US 2019/0083520 A1 to Emory University teaches a pharmaceutical composition (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I) for the treatment of 2019nCoV/SARS-CoV-2 infection (Para. [0305], In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus; i.e., The present invention is useful for treating a wide range of coronavirus variants which inherently includes 2019nCoV/SARS-CoV-2 and COVID-19); COVID-19 (Para. [0305]), comprising a pharmaceutically acceptable excipient (Para. [0308], a pharmaceutical composition comprises a pharmaceutically acceptable excipient, such as a pharmaceutically acceptable carrier; Claim 1) and a compound of Formula XXI (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and a compound having the core structure of Formula I (Claim 16, see shown structure); a method of treating 2019nCoV/SARS-CoV-2 virus infection and COVID-19 in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); a method of preventing 2019nCoV/SARS-CoV-2 virus infection in a patient in need thereof, COVID-19 in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection and COVID-19 (Claim 1, Para. [0305]), comprising a pharmaceutically acceptable excipient (Para. [0308] and a compound with the following structure shown (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931); and one or more antiviral agent selected from abacavir (Para. [0352], in combination with another antiviral agent(s) such as abacavir); a method of treating a 2019nCoV/SARS-CoV-2 infection, and COVID-19 (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Para. [0305], human coronavirus, SARS coronavirus, MERS coronavirus), comprising administering an effective amount of a compound with the following structure shown (Para.

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[0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and one or more antiviral agent selected from abacavir (Para. [0352], in combination with another antiviral agent(s) such as abacavir).

The inventions listed in Groups I+ therefore lack unity under Rule 13 because they do not share a same or corresponding special technical feature.

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<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>

Regarding Claim 9, Emory '520 discloses the pharmaceutical composition of claim 8, wherein R1, R2, R3, and R5 are each independently H (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Regarding Claim 10, Emory '520 discloses the pharmaceutical composition of claim 8, wherein R1 is H (Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Regarding Claim 51, Emory '520 discloses a method of treating COVID in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306], In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV) comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Regarding Claim 55, Emory '520 discloses a method of preventing COVID in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306], In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV) comprising administering an effective amount of a compound with the structure to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Regarding Claim 59, Emory '520 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claim 1, Paras. [0305]-[0306]), comprising a pharmaceutically acceptable excipient (Para. [0308]) and a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931) and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353], In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 60, Emory '520 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claim 1, Paras. [0305]-[0306]), comprising a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353], In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 63, Emory '520 discloses a pharmaceutical composition for the treatment of COVID (Claim 1, Paras. [0305]-[0306]), comprising a pharmaceutically acceptable excipient and a compound with the following structure shown and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353], In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 64, Emory '520 discloses a pharmaceutical composition for the treatment of COVID (Claim 1, Paras. [0305]-[0306]), comprising a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931), and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353], In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '520 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

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Claims 47, 67, 69, and 75 lack an inventive step under PCT Article 33(3) as being obvious over US 2019/0083520 to Emory University (hereinafter, "Emory '520").

Regarding Claim 47, Emory '520 discloses a method of treating CoV/SARS-CoV virus infection in a patient in need thereof (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306]). In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV) comprising administering an effective amount of a compound with the structure shown to the patient (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Emory '520 fails to explicitly disclose treating 2019nCoV/SARS-CoV-2 infection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '520 to treat 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 67, Emory '520 discloses a method of treating a CoV/SARS-CoV infection (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306]). In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV), comprising administering an effective amount of a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931) and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353]). In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

Emory '520 fails to explicitly disclose treating of 2019nCoV/SARS-CoV-2 infection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '520 to treat 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 69, Emory '520 discloses a method of treating COVID (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306]). In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV), comprising administering an effective amount of a compound with the following structure shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931) and one or more antiviral agent selected from the group consisting of NITD008 (Claim 21, The pharmaceutical composition of claim 1, further comprising a non-CNS targeting antiviral compound; Para. [0353]). In exemplary embodiments, the non-CNS targeting antiviral compound is, for example, NITD008, BCX4430, and the like).

Emory '520 fails to explicitly disclose treating of COVID-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '520 to treat COVID-19, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Regarding Claim 75, Emory '520 discloses a method of treating or preventing infections caused by CoV/SARS-CoV (Para. [0012], methods of treating or preventing a viral infection comprising administering an effective amount of a compound or pharmaceutical composition; Paras. [0305]-[0306]). In some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus ... MERS-COV), comprising administering to a host in need an effective amount of the compound shown (Para. [0012]; Claim 16, see shown structure; Para. [0362], see structure of EIDD-1931).

Emory '520 fails to explicitly disclose treating or preventing infections caused by 2019-nCoV/SARS-CoV-2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '520 to treat or prevent infections caused by 2019-nCoV/SARS-CoV-2, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Paras. [0305]-[0306]).

Claims 1, 2, 4, 8-10, 47, 51, 55, 59, 60, 63, 64, 67, 69, and 75 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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2nd invention

Novelty (N)	Claims	48, 52, 54, 56, 68, 70, 74	YES
	Claims	1, 3, 5, 8, 13, 17, 20, 61, 62, 65, 66	NO
Inventive step (IS)	Claims	None	YES
	Claims	1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74	NO
Industrial applicability (IA)	Claims	1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, 74	YES
	Claims	None	NO

Claims 1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, and 74 (as best interpreted) have been analyzed subject to the restriction that the claims read on the Formula XXI as described in the Response to the Invitation to Pay Additional Fees in the International Application dated 05 May 2021 as further restricted to the variable definitions listed below. The claims are restricted to a pharmaceutical composition for the treatment of 2019nCoV/SARS-CoV-2 infection, comprising a pharmaceutically acceptable excipient and a compound of Formula XXI, or a tautomer thereof, or a pharmaceutical salt or physiological salt thereof, wherein R1 is R6C(O), where R6 is alkyl.

Claims 1, 3, 5, 8, 13, 17, 20, 61, 62, 65, and 66 lack novelty under PCT Article 33(2) as being anticipated by WO 2019/113462 to Emory University (hereinafter, "Emory '462").

Regarding Claim 1, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I; Claim 41; Pg. 105, Lns. 17-20, in some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24, pharmaceutical composition comprises a pharmaceutically acceptable excipient, such as a pharmaceutically acceptable carrier, and an exemplary compound described herein; Claim 1) and a compound of Formula XXI, wherein R1 is R6C(O), where R6 is alkyl (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 3, Emory '462 discloses the pharmaceutical composition of claim 1, wherein the compound has the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

Regarding Claim 5, Emory '462 discloses a pharmaceutical composition for the treatment of COVID (Claim 1, A pharmaceutical composition comprising a pharmaceutically acceptable excipient and a compound of Formula I; Claim 41; Pg. 105, Lns. 17-20, in some embodiments, the subject is at risk of, exhibiting symptoms of, or diagnosed with ... human coronavirus, SARS coronavirus, MERS coronavirus), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24; Claims 1 and 41) and a compound with the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 8, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24; Claims 1 and 41) and a compound of Formula I wherein X is CH₂; Y is CR¹; Z is CR²; R¹ is hydrogen; R² is hydrogen; R1 is R6C(O), where R6 is alkyl; R2, R3, and R5 are each independently H (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 13, Emory '462 discloses the pharmaceutical composition of claim 8, wherein the compound is selected from the fifth shown structure (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

Regarding Claim 17, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claims 1 and 41; Pg. 105, Lns. 17-20), wherein the compound is a compound of Formula II, wherein X is CH₂; Y is CR¹; Z is CR²; R¹ is hydrogen; R² is hydrogen; R1 is R6C(O), where R6 is alkyl; R2, R3, and R5 are each independently H (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

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Regarding Claim 20, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24; Claims 1 and 41) and a compound of Formula III, wherein X is CH₂; Z is CRⁿ; Rⁿ is hydrogen; R₁ is R₆C(O), where R₆ is alkyl; R₂, R₃, and R₅ are each independently H (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 61, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24; Claims 1 and 41) and a compound with the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 62, Emory '462 discloses a pharmaceutical composition for the treatment of CoV/SARS-CoV infection (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a compound with the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

In regards to for the treatment of 2019nCoV/SARS-CoV-2 infection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 65, Emory '462 discloses a pharmaceutical composition for the treatment of COVID (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a pharmaceutically acceptable excipient (Pg. 106, Lns. 21-24; Claims 1 and 41) and a compound with the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 66, Emory '462 discloses a pharmaceutical composition for the treatment of COVID (Claims 1 and 41; Pg. 105, Lns. 17-20), comprising a compound with the following structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

In regards to for the treatment of COVID-19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, it meets the claim. In this case, the composition of Emory '462 may be used to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Claims 48, 52, 54, 56, 68, 70, and 74 lack an inventive step under PCT Article 33(3) as being obvious over WO 2019/113462 A1 to Emory University (hereinafter, "Emory '462").

Regarding Claim 48, Emory '462 discloses a method of treating CoV/SARS-CoV virus infection in a patient in need thereof (Claims 47, 50 and 51, A method of treating or preventing a viral infection comprising administering in effective amount of a compound of any one of claims 1-42 to a subject in need thereof ... wherein the viral infection is a human coronavirus, SARS coronavirus, and MERS coronavirus; Claim 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) to the patient (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5). Emory '462 fails to explicitly disclose treating 2019nCoV/SARS-CoV-2 infection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to treat 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

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Regarding Claim 52, Emory '462 discloses a method of treating COVID in a patient in need thereof (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) to the patient (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5).

Emory '462 fails to explicitly disclose treating COVID-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to treat COVID-19, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 54, Emory '462 discloses a method of preventing CoV/SARS-CoV virus infection in a patient in need thereof (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) to the patient (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5).

Emory '462 fails to explicitly disclose preventing 2019nCoV/SARS-CoV-2 infection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to prevent 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 56, Emory '462 discloses a method of preventing COVID in a patient in need thereof (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) to the patient (Claims 47, 50, 51, and 58; Pg. 105, Lns. 2-5).

Emory '462 fails to explicitly disclose treating COVID-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to prevent COVID-19, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 68, Emory '462 discloses a method of treating a CoV/SARS-CoV infection (Claims 47, 50 and 51, A method of treating or preventing a viral infection comprising administering in effective amount of any one of claims 1-42 to a subject in need thereof ... wherein the viral infection is a human coronavirus, SARS coronavirus, and MERS coronavirus; Claim 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

Emory '462 fails to explicitly disclose treating 2019nCoV/SARS-CoV-2 infection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to treat 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 70, Emory '462 discloses a method of treating COVID (Claims 47, 50 and 51, A method of treating or preventing a viral infection comprising administering in effective amount of a compound of any one of claims 1-42 to a subject in need thereof ... wherein the viral infection is a human coronavirus, SARS coronavirus, and MERS coronavirus; Claim 58; Pg. 105, Lns. 2-5) comprising administering an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41) and one or more antiviral agent selected from the group consisting of abacavir (Pg. 118, Lns. 1-14, In certain embodiments, the exemplary compounds and pharmaceutical compositions can be administered in combination with another antiviral agent(s) such as abacavir ...).

Emory '462 fails to explicitly disclose treating COVID-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to treat COVID-19, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

Regarding Claim 74, Emory '462 discloses a method of treating or preventing infections caused by CoV/SARS-CoV infection (Claims 47, 50 and 51, A method of treating or preventing a viral infection comprising administering in effective amount of a compound of any one of claims 1-42 to a subject in need thereof ... wherein the viral infection is a human coronavirus, SARS coronavirus, and MERS coronavirus; Claim 58; Pg. 105, Lns. 2-5) comprising administering to a host an effective amount of a compound with the structure shown (Pg. 136, Lns. 23-24, Example 10: Synthesis of EIDD-2801, see structure of EIDD-2801; Claim 41).

Emory '462 fails to explicitly disclose treating or preventing infections caused by 2019nCoV/SARS-CoV-2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Emory '462 to treat or prevent 2019nCoV/SARS-CoV-2 infection, since omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. The motivation for doing so would be to treat any and all human coronavirus, SARS coronavirus, MERS coronavirus, MERS-COV infections (Pg. 105, Lns. 17-20).

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Claims 1, 3, 5, 8, 13, 17, 20, 48, 52, 54, 56, 61, 62, 65, 66, 68, 70, and 74 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Search History:

Limited Classification Search

The Patent Analyst performed a limited classification search within the following US, IPC, CPC, ECLA, or F-Term classification areas:

CPC Class/Subclass(es): A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.05)

IPC(8) Class/Subclass(es): A61K 31/7064; A61K 31/7068; A61P 31/12; C07H 19/04; C07H 19/06; C07H 19/067 (2021.01)

U.S. Class/Subclass(es): 514/49

See Global Search Results.

Global Patent Literature Text Search

The Patent Analyst performed the following global text search, which was not limited by classification but may or may not have been limited by other criteria:

Questel Orbit: <https://www.orbit.com>

#	Search query	Results
1	(SPA/BNT="EMORY UNIVERSITY-646693")	1342
2	(HYDROXYCYTIDIN+ AND (ANTIVIRAL+ OR ANTI VIRAL+))/TI/ABS	8
3	1 AND 2	6
4	(EIDD 1931)/TI/ABS/CLMS/TX	11
5	(EIDD 2801)/TI/ABS/CLMS/TX	10
6	1 AND (4 OR 5)	6
7	3 AND 6	4
8	(COVID19 OR COVID 19)/TI/ABS/CLMS	1278
9	7 AND 8	0
10	(COVID19 OR COVID 19)/TI/ABS/CLMS/TX	4409
11	10 AND 7	0
12	10 AND (4 OR 5)	7
13	2 AND 12	1
14	(A61K-031/7068 OR A61K-031/7064)/CPC OR (A61K-031/7068 OR A61K-031/7064)/IPC	5694
15	(A61P-031/12)/CPC OR (A61P-031/12)/IPC	35992
16	(C07H-019/067 OR C07H-019/06 OR C07H-019/04)/CPC OR (C07H-019/067 OR C07H-019/06 OR C07H-019/04)/IPC	5464
17	(514049000)/PCLM	461

18	10 AND (15 OR 16 OR 17)	101
19	(HYDROXYCYTIDIN+)/TI/ABS/CLMS/TX	208
20	18 AND 19	1

Google Patents: <https://patents.google.com>

#	Search query	Results
1	treat covid19	68805
2	(treat covid19) (hydroxycytidine)	392
3	(treat covid19) (hydroxycytidine) ((EIDD 1931) OR (EIDD 2801))	30

Computer Accessed Text Databases Searched

The Patent Analyst searched the following computer accessed text databases:

PubChem.gov (NCBI): <https://pubchem.ncbi.nlm.nih.gov/>

#	Search query	Results
1	<chem>C1(C(C(C(O1)N2C=CC(=NC2=O)N(O[H])[H])O[H])O[H])CO[H]</chem>	1
2	<chem>C1(C(C(C(O1)N2C=CC(=NC2=O)N(O[H])[H])O[H])O[H])COC(=O)C</chem>	196

Google Scholar: <https://scholar.google.com/>

#	Search query	Results
1	(treat covid19)	19900
2	(treat covid19) (n-hydroxy hydroxycytidine)	10
3	(treat covid19) (hydroxycytidine) ((EIDD 1931) OR (EIDD 2801))	148

Date search was completed: 19 May 2021

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