

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MET10638P00651PC		FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US23/30689	International filing date (day/month/year) 21 August 2023 (21.08.2023)	(Earliest) Priority Date (day/month/year) 19 August 2022 (19.08.2022)
Applicant MIRATI THERAPEUTICS, 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 4 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/US23/30689

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.: 13-22, 24-36
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:

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.:

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/US23/30689

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Pharmaceutical compositions in solid form comprising adagrasib, suitable for oral dosage to treat subjects having cancer; as well as methods of manufacturing the compositions, and methods of treating cancer. In one embodiment, the present invention provides a pharmaceutical composition, in solid form, suitable for oral administration to a subject, including but not limited to a human subject, which comprises adagrasib or a salt thereof, wherein the solid pharmaceutical composition, comprises: adagrasib, microcrystalline cellulose, mannitol, crospovidone, colloidal silicon dioxide and magnesium stearate; wherein the solid pharmaceutical composition is in the form of a tablet; and wherein the solid pharmaceutical composition further comprises a film coat.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US23/30689

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61K 31/33; A61K 9/20; A61K 45/06 (2023.01)

ADD. A61P 35/00 (2023.01)

CPC - INV. A61K 31/33; A61K 9/0053; A61K 9/20; A61K 45/06

ADD. A61P 35/00

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 database consulted during the international search (name of database 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 2010/0310651 A1 (MITTAL, B) 09 December 2010; Abstract; paragraphs [0016], [0024]-[0027], [0030], [0032], [0037], [0041], [0097], [0101], [0122], [0123], [0117], [0171]; claims 1 and 3	1-12, 23
A	US 2019/0224175 A1 (SALIX PHARMACEUTICALS LTD) 25 July 2019; Abstract; paragraphs [0014], [0031], [0060]; table 2; claim 1	1-12, 23
A	US 2015/0196493 A1 (MCNEIL-PPC INC.) 16 July 2015; Abstract; paragraphs [0013], [0014], [0018], [0031], [0068], [0106]	1-12
A	US 2005/0051922 A1 (NANGIA, A ET AL) 10 March 2005; Abstract; paragraphs [0017]-[0024], [0035], [0044], [0058], [0060], [0077], [0079]	23
P,X	CN 115521312 A (SHANGHAI ACEBRIGHT PHARMA GROUP CO LTD et al.) 27 December 2022	1-12, 23

☐ 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

29 October 2023 (29.10.2023)

Date of mailing of the international search report

FEB 26 2024

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

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