

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

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

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

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

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2024/042221

International filing date (day/month/year)
14.08.2024

Priority date (day/month/year)
15.08.2023

International Patent Classification (IPC) or both national classification and IPC
INV. C07D405/12 A61P35/00 A61K31/506

Applicant
SCORPION THERAPEUTICS, INC.

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

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

2. FURTHER ACTION

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

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

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

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Lauro, Paola

Telephone No. -0



Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☒ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)),
 - ☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-37</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-37</u>
Industrial applicability (IA)	Yes: Claims	<u>1-37</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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:

see separate sheet

1 **Re Item V**

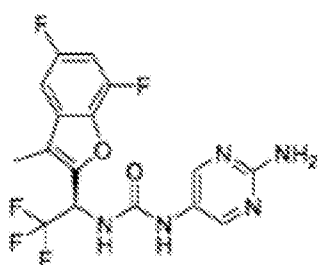
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.1 Reference is made to the following document:

D1 WO 2022/265993 A1 (SCORPION THERAPEUTICS INC [US]) 22
December 2022 (2022-12-22)cited in the application

1.2 Claims 34-37 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT. The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

1.3 The present application relates to crystalline forms of the following compound A:



methods for their preparation and medical uses thereof.

1.4 **Novelty**

D1 discloses on page 408 the synthesis of Compound A (see compound 80 in D1). On page 140 of the present application, reference is made to D1 disclosing methods for preparing the crystalline forms of the present application. It is queried whether D1 discloses the same crystalline form as the generic crystalline form of compound A claimed in the present application. In addition, on page 141 of the present application the initial compound A prior to any crystallization trials is assigned to be Form 1*; Form 1* appears not to be a crystalline form and therefore is considered to be anticipated by D1. The Applicant is invited to provide evidence that the claimed compounds differ from compound A disclosed in D1. At present, in the absence of evidence to the contrary, in view of the statements in the description of the current application, the subject-matter of claims 1 to 37 is considered to be anticipated by D1 (Art. 33 (2) PCT).

1.5 Inventive step

In view of the novelty objection, no inventive step can be acknowledged (Art. 33 (3) PCT). In case the Applicant were able to demonstrate that the currently claimed crystalline forms of compound A differ from compound A disclosed in D1, then evidence of advantages re the compound disclosed in D1 should be provided, since the provision of polymorphic forms of a known compounds is routine in the pharmaceutical field and the activity of compound A as PI3K inhibitor is already known from D1.

2 Re Item VI

Certain documents cited

The following document:

- D2 WO 2024/097636 A1 (SCORPION THERAPEUTICS INC [US]) 10 May 2024 (2024-05-10)

was published after the priority date of the current application and it is therefore not taken into account for the purpose of the present opinion.

3 Re Item VIII

Certain observations on the international application

- 3.1 The crystalline forms I should be characterized in the claims by a number of peaks which allows the identification of the specific crystalline form of compound A. Although in the description on page 141, form I* is defined as compound A before any crystalization step, in the claims compound I* is characterized as being crystalline. Irrespective of such an inconsistency with the definition given in the description, it is noted that the crystalline form I* in the claims is not defined by a combination of peaks but only by single peaks which do not allow to distinguish it from form I (see e.g. claim 23, 25, 26).