

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

NOV 17 2023

Applicant's or agent's file reference
SLI-013WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 23/68239

International filing date (day/month/year)

09 June 2023 (09.06.2023)

Priority date (day/month/year)

10 June 2022 (10.06.2022)

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

IPC - INV. C07D 405/12, C07D 405/14, C07D 413/12, C07D 471/04, C07D 491/056 (2023.01)

ADD. C07D 519/00, A61P 11/00 (2023.01)

CPC - INV. C07D 405/12, C07D 405/14, C07D 413/12, C07D 471/04, C07D 491/056

ADD. C07D 519/00, A61P 11/00

Applicant SIONNA THERAPEUTICS

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, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion,

06 November 2023 (06.11.2023)

Authorized officer

Kari Rodriguez

PCT Help Desk

Telephone No. 571-272-4300

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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 43*bis*.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.
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13ter.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:

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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. 11-47, 49-55

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. 11-47, 49-55 are so unclear that no meaningful opinion could be formed (*specify*):

because they are dependent claims and are 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. 11-47, 49-55

☐ 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.

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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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I+: Claims 1-10 and 48, directed to a compound of claim 1, formula I or II. The compound of claim 1 will be searched to the extent that it encompasses the first species of claim 1, represented by a compound of formula I, wherein A is 3 membered carbocyclyl; L is a bond; W is O; X1 is N; X2 is CH₂; Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Y4 is -C(H)=; Z is -C(H)=; Rb is CN; Re1 is hydrogen; Re2 is hydrogen; m is 0; n is 0 (wherein optional groups are omitted). It is believed that claims 1 and 3/1 read on this first named invention, and thus these claims will be searched without fee. This first named invention has been selected based on the guidance set forth in section 10.54 of the PCT International Search and Preliminary Examination Guidelines. Applicant is invited to elect additional compounds of claim 1, wherein each additional compound elected will require one additional invention fee. Applicants must specify the claims that encompass any additionally elected compound. Applicants must further indicate, if applicable, the claims which encompass 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. Additionally, an exemplary election wherein different actual variables are selected is suggested. An exemplary election would be a compound of formula I A is 3 membered carbocyclyl; L is a bond; W is S; X1 is N; X2 is CH₂; Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Y4 is -C(H)=; Z is -C(H)=; Rb is CN; Re1 is hydrogen; Re2 is hydrogen; m is 0; n is 0 (wherein optional groups are omitted) (i.e., claims 1 and 4/1).

The group of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group I+ includes the technical feature of a unique compound of formula I or II, which is not required by any other invention of Group I+.

Common technical features:

The inventions of Groups I+ share the technical feature of a compound of formula I or II.

These shared technical features, however, do not provide a contribution over the prior art, as being obvious over US 2020/0369663 A1 to Fondazione Istituto Italiano Di Tecnologia (hereinafter Fondazione) in view of US 2016/0046574 A1 to Janssen Pharmaceutica NV (hereinafter Janssen). Fondazione discloses a compound of formula I wherein A is phenyl; L is O; X1 is C(H); X2 is CH₂; Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Y4 is -C(H)=; Z is -C(H)=; Ra is COOH; Rb is C1 haloaliphatic; m is 1; n is 1 (para [0515]; (pg. 102) compound 170), but does not disclose a linker moiety comprising W or Re1 or Re2. However, Janssen discloses similar linker moieties for connecting 2,2-difluoro-1,3-benzodioxoles to phenyl rings via a linker wherein W is O and Re1 and Re2 are hydrogen (para [0328]). It would have been obvious to one with skill in the art to prepare derivatives of the compound disclosed by Fondazione, comprising similar heteroalkyl linker moieties utilized for connecting similar 2,2-difluoro-1,3-benzodioxoles compounds, as disclosed by Janssen.

As said compound was known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the inventions of Groups I+. The inventions of Group I+ thus lack unity under PCT Rule 13.

Item 4 Cont.: Claims 11-47, 49-55 have been found to be unsearchable because they are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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. 1, 3/1

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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

1. Statement

Novelty (N)	Claims	1, 3/1	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1, 3/1	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1, 3/1	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1 and 3/1 meet the criteria set out in PCT Article 33(2)-(3) because the prior art does not teach or fairly suggest the subject matter claimed.

Regarding Claim 1, US 2020/0369663 A1 to Fondazione Istituto Italiano Di Tecnologia et al. (hereinafter "Fondazione") discloses a compound of formula I wherein X2 is CH2; Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Y4 is -C(H)=; Z is -C(H)= (para [0515]; (pg. 102) compound 170), but does not disclose wherein A is 3 membered carbocyclyl; L is a bond; W is O; X1 is N; Rb is CN; Re1 is hydrogen; Re2 is hydrogen; m is 0 and n is 0.

US 2016/0046574 A1 to Janssen Pharmaceutica NV (hereinafter "Janssen") discloses a similar compound wherein Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Z is -C(H)=; W is O and Re1 and Re2 are hydrogen (para [0328]), but does not disclose a compound of formula I wherein A is 3 membered carbocyclyl; L is a bond; X1 is N; X2 is CH2; Y4 is -C(H)=; Rb is CN; m is 0 and n is 0.

WO 2014/152738 A1 to BRISTOL-MYERS SQUIBB COMPANY et al. (hereinafter "Bristol") discloses a compound comprising a pyrazole moiety wherein Rb is CN and a benzodioxole moiety wherein Z is -C(H)= (pg. 165, Table: compound 123), but does not disclose a compound of formula I A is 3 membered carbocyclyl; L is a bond; W is O; X1 is N; X2 is CH2; Y1 is -C(H)=; Y2 is -C(H)=; Y3 is -C(H)=; Y4 is -C(H)=; Re1 is hydrogen; Re2 is hydrogen; m is 0 and n is 0.

Regarding Claim 3/1, this is a dependent claim depending from claim 1 and therefore, meets the criteria set forth in PCT Article 33(2) and 33(3).

Claims 1 and 3/1 have industrial applicability as defined by PCT Article 33(4) because the subject matter could be made or used in industry.