

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

**DANA M. GORDON
FOLEY HOAG LLP
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2600
UNITED STATES OF AMERICA**

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing

(day/month/year)

13 February 2025 (13.02.2025)

Applicant's or agent's file reference

SNX-02625

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2024/055181

International filing date (day/month/year)

08 November 2024 (08.11.2024)

Priority date (day/month/year)

10 November 2023 (10.11.2023)

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

IPC: **A61K 31/395** (2024.01); **A61K 31/404** (2024.01); **A61K 31/539** (2024.01); **A61K 31/33** (2024.01)

CPC: **A61K 31/395; A61K 31/404; A61K 31/539; A61K 31/539**

Applicant

SENSORIUM 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 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

**COMMISSIONER FOR PATENTS
MAIL STOP PCT, ATTN: ISA/US
P.O. Box 1450
Alexandria, VA 22313-1450
UNITED STATES OF AMERICA**

Date of completion of this opinion

12 December 2024 (12.12.2024)

Authorized officer

KARI RODRIQUEZ

Facsimile No. **571-273-8300**

Telephone No. **PCT Help Desk:
571-272-4300**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/055181

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 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.
 - 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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/055181

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. 2,4,5,7,9-11,13-21

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. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ 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. 2,4,5,7,9-11,13-21

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

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

☐ See Supplemental Box for further details.

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.

Group I+: Claims 1-20 directed to a compound represented by the structure of formula I including salts thereof. Claim 1 will be searched to the extent that it encompasses the first species of a compound represented by the structure of formula I, wherein Ring A is the first cyclohexene ring in the instant claim 1, m is 0; each R2, R3 and R4 is H and R5 is C1-alkyl. It is believed that claims 1,3,6, 8,12 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 the compound represented by the structure of formula I, wherein Ring A is the first cyclohexene ring in the instant claim 1, m is 0; Each R2 and R3 are each alkyl; R4 is H and R5 is C1-alkyl. (Claims 1, 3, 6, 11,12).

Group II: Claim 21 directed to method of treating a central nervous condition, comprising administering to a subject in need thereof an effective amount of a compound of any of claims 1-20.

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 represented by the structure of formula I, which is not required by any other invention of Group I+ or Group II.

Group II includes the technical feature of method of treating a central nervous condition, comprising administering to a subject in need thereof an effective amount of a compound of any of claims 1-20, which is not required by any other invention of Group I+.

Common technical features:

The inventions of Group I+ and Group II share the technical feature of a compound represented by the core structure of formula I.

These shared technical features, however, do not provide a contribution over the prior art, as being anticipated by Pubchem 463506716 (hereinafter "Pubchem"). Pubchem teaches the core structure of formula I (pg. 2, structure).

As said compound and compositions were 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+ and Group II. The inventions of Group I+ and Group II thus lack unity under PCT Rule 13.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/055181

Box No. IV Lack of unity of invention

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. 1,3,6,8,12

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/055181

Box No. V

Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,3,6,8,12	YES
	Claims	none	NO
Inventive step (IS)	Claims	1,3,6,8,12	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1,3,6,8,12	YES
	Claims	none	NO

2. Citations and explanations:

----- EXPLANATION -----

Claims 1,3,6,8,12 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed subject matter, specifically a compound of formula I wherein R4 is selected from H, C1-4 alkyl or C1-6 haloalkyl.

As to Claim 1,

Pubchem 463506716 (hereinafter “Pubchem”) discloses a compound of formula I wherein Ring A is the first cyclohexene ring of the instant claim 1, wherein the astericks denote attachment points of ring A to the compound of formula I, m is 0, and R5 is C1-alkyl (pg. 2, structure). Pubchem does not disclose R2, R3 and R4 as H.

US 2023/0159455 A1 to SENSORIUM THERAPEUTICS, Inc. (hereinafter “Sensorium”) discloses a compound of formula I, wherein m is 0 and R5 is C1-alkyl (pg. 16, first column, first structure). Sensorium does not disclose Ring A is the first cyclohexene ring of the instant claim 1 and R2, R3 as H and R4 as H.

US 2005/0239841 A1 to BROWNING, et.al. (hereinafter “Browning”) discloses a compound of formula I (para [0042], general formula I) wherein m is 0 (para [0042]; [0052];[0053], general formula I, R8 and R9 are each H);each of R2 and R3 is H (para [0042];[0045], General Formula I, R1 and R2 are each H) and R5 is C1-alkyl (para [0042];[0047], General Formula I, R3 is C1-alkyl). Browning does not disclose Ring A as the first cyclohexene ring of the instant claim 1 and R4 as H.

US 2012/0225845 A1 to KLEIN, et.al. (hereinafter “Klein”) discloses a compound of formula I, wherein R2 and R2 and R3 are each H (para [0009];[0010], General Formula II, R3 and R4 can each be OH); R4 is H (para [0009];[0012], General Formula II, R8 is hydro). Klein does not disclose Ring A as the first cyclohexene ring of the instant claim 1, the phenyl ring bound at the bridge carbon of the tetrahydroindole, m as 0 and R5 as methyl.

Claims 3,6,8 and 12 are dependent from claim 1 and therefore, meet the criteria set out in PCT Article 33(2)-(3).

Claims 1,3,6,8,12 have industrial applicability as defined by PCT Article 33(4), because the subject matter can be made or used in industry.