

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing

(day/month/year)

03.12.2025

Applicant's or agent's file reference

120983P1535PC

IMPORTANT NOTIFICATION

International application No.

PCT/EP2024/077295

International filing date (day/month/year)

27.09.2024

Priority date (day/month/year)

28.09.2023

Applicant

Bayer Aktiengesellschaft

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 120983P1535PC	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2024/077295	International filing date (day/month/year) 27.09.2024	Priority date (day/month/year) 28.09.2023	
International Patent Classification (IPC) or national classification and IPC INV. A61P9/00			
Applicant Bayer Aktiengesellschaft			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>9</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ a total of <u>19</u> sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2). ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)). b. ☐ a separate electronic file containing a sequence listing (<i>sent to the International Bureau only</i>)			
4. This report contains indications relating to the following items: ☒ Box No. I Basis of the report ☐ 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 Article 35(2) with regard to novelty, inventive step or 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			
Date of submission of the demand 25.07.2025		Date of completion of this report 03.12.2025	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0		Authorized officer Bedel, Christian Telephone No. +49 89 2399-2506 	

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ 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 (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-266 as originally filed

Claims, Numbers

1-21 filed in electronic form on

07-08-2025

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
 - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4bis and 70.2(e)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2024/077295

6. ☒ With regard to top-up searches (Rules 66.1 *ter* and 70.2(f)):
- ☒ A top-up search was carried out by this Authority on 05.09.2025 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
 - ☐ Additional relevant documents have been discovered during the top-up search.
 - ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded".

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>6-10</u>
	No: Claims	<u>1-5, 11-21</u>
Inventive step (IS)	Yes: Claims	<u>6-10</u>
	No: Claims	<u>1-5, 11-21</u>
Industrial applicability (IA)	Yes: Claims	<u>1-21</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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

Re Item V

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

1 Preliminary remark

The subject-matter of claim 21 concerns a method of treatment and is therefore 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.

Patentability, in particular novelty and inventive step, of claim 21 has been assessed on the basis of a purpose-limited product claim taking into account the alleged effects of the compound/composition

2 The amendments filed in PCT Chapter phase are in conformity with Article 34.2)b) PCT.

3 Reference is made to the following documents:

- D1 WO 2006/058905 A1 (DEVGEN NV [BE]; BLOM PETRA [BE] ET AL.)
8 June 2006 (2006-06-08)
- D2 WO 2019/002074 A1 (BAYER AG [DE]; BAYER PHARMA AG [DE])
3 January 2019 (2019-01-03)
- D3 DATABASE CHEMCATS [Online]6 April 2023 (2023-04-06),"RN
2974543-03-6",XP093225534,Database accession no. 0300466902
- D4 DATABASE CHEMCATS [Online]6 April 2023 (2023-04-06),"RN
1358081-36-3",XP093225514,Database accession no. 1502615470
- D5 DATABASE CHEMCATS [Online]6 April 2023 (2023-04-06),"RN
1954022-51-5",XP093225507,Database accession no. 1846083409
- D6 DATABASE CHEMCATS [Online]6 April 2023 (2023-04-06),"RN
2974525-71-6",XP093225529,Database accession no. 0867745744
- D7 DATABASE CHEMCATS [Online]6 April 2023 (2023-04-06),"RN
2394582-60-0",XP093225464,Database accession no. 1709760042

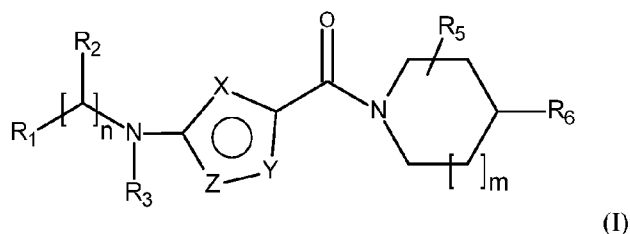
D8 WO 2021/089683 A1 (BAYER AG [DE]) 14 May 2021 (2021-05-14)

D9 WO 2005/118579 A2 (ASTRAZENECA AB [SE]; ASTRAZENECA UK LTD [GB] ET AL.) 15 December 2005 (2005-12-15)

D10 WO 2022/048631 A1 (INNOVSTONE THERAPEUTICS LTD [CN]) 10 March 2022 (2022-03-10)

4 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

4.1 Present application concerns in claim 1 a compound of general formula (I):



in which

X is S, N or O;

Y is N, S or O,

where, when X is S, Z is N;

where, when X is O, Z is N;

Y is CR₄, O or NR₄,

where, when X is N and Z is N, Y is O;

where, when X is S, Y is CR₄ or NR₄;

R₁ is 5- to 10-membered heteroaryl, phenyl, (C₄-C₁₀)-heterocycloalkyl or (C₃-C₁₀)-cycloalkyl,

in which 5- to 10-membered heteroaryl may be substituted by 1 to 3 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy, halogen;

where (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

where (C₁-C₄)-alkoxy may be up to trisubstituted by halogen,

in which phenyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₃-C₅)-cycloalkyl, (C₁-C₄)-alkoxy, cyano, hydroxy, halogen;

where (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₃-C₁₀)-cycloalkyl and (C₄-C₁₀)-heterocycloalkyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₃-C₅)-cycloalkyl, (C₁-C₄)-alkoxy, cyano, hydroxy, halogen;

where (C₁ -C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₃ -C₁₀)-cycloalkyl and (C₄ -C₁₀)-heterocycloalkyl may be fused to 5- to 10-membered heteroaryl,

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁ -C₄)-alkyl, (C₁ -C₄)-alkoxy and halogen;

R₂ is hydrogen, (C₁ -C₄)-alkyl or (C₃ -C₅)-cycloalkyl;

in which (C₁ -C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₁ -C₄)-alkyl may be substituted by cyano or (C₁ -C₄)-alkoxy,

in which (C₃ -C₅)-cycloalkyl may be up to trisubstituted by halogen,

or

together with the carbon atom to which R₂ is bonded forms a (C₃ -C₄)-cycloalkyl ring,

or

R₁ and R₂ together form a (Cs-Cs)-cycloalkyl or (C₅ -C₁₀)-heterocycloalkyl ring,

in which (Cs-Cs)-cycloalkyl may be fused to 5- to 10-membered heteroaryl,

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁ -C₄)-alkyl, (C₁ -C₄)-alkoxy and halogen;

in which (C₃ -C₁₀)-heterocycloalkyl may be fused to 5- to 10-membered heteroaryl,

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁ -C₄)-alkyl, (C₁ -C₄)-alkoxy and halogen;

R₃ is hydrogen, (C₁ -C₄)-alkyl,

in which (C₁ -C₄)-alkyl may be up to trisubstituted by halogen,

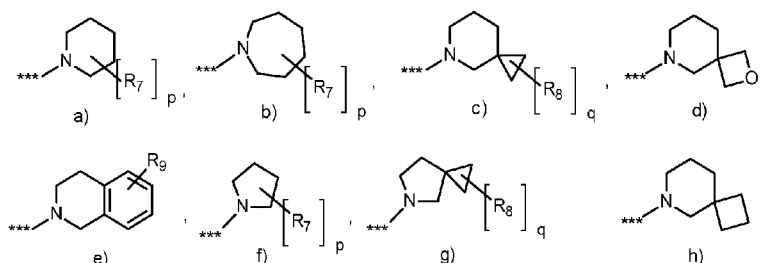
R₄ in CR₄ is hydrogen, (C₁ -C₄)-alkyl, (C₃ -C₄)-cycloalkyl, phenyl, halogen;

in which (C₁ -C₄)-alkyl may be up to trisubstituted by halogen and phenyl may be substituted by halogen,

in NR₄ is absent or is hydrogen, (C₁ -C₄)-alkyl, (C₃ -C₄)-cycloalkyl, phenyl; in which (C₁ -C₄)-alkyl may be up to trisubstituted by halogen and phenyl may be substituted by halogen,

Rs is hydrogen, (C₁ -C₄)-alkyl, (C₁ -C₄)-alkoxy, halogen,

R₆ is a group of formula a), b), c), d), e), f) or g)

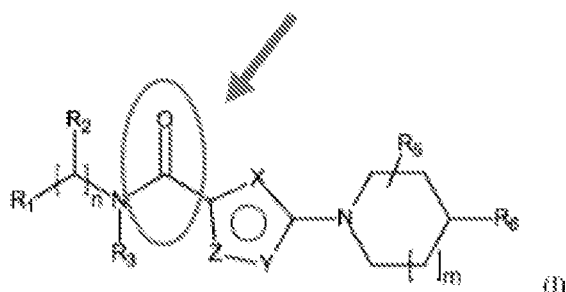


in which *** marks the attachment to the adjacent piperidine ring,

in which R₇ is hydrogen, (C₁-C₄)-alkyl, (C₃-C₄)-cycloalkyl, (C₁-C₄)-alkoxy, (C₃-C₄)-cycloalkoxy, phenyl,
where (C₁-C₄)-alkyl may be substituted by (C₃-C₄)-cycloalkyl, (C₁-C₄)-alkoxy, (C₃-C₄)-cycloalkoxy and up to trisubstituted by halogen,
where (C₁-C₄)-alkoxy may be substituted by (C₃-C₄)-cycloalkyl and up to trisubstituted by halogen,
where (C₃-C₄)-cycloalkyl may be substituted by monofluoromethyl, difluoromethyl or trifluoromethyl and up to disubstituted by halogen,
where (C₁-C₄)-alkoxy may be substituted by (C₃-C₄)-cycloalkyl and up to trisubstituted by halogen,
where (C₃-C₄)-cycloalkyl may be mono- or disubstituted by halogen,
where (C₃-C₄)-cycloalkoxy may be up to disubstituted by halogen, in which R₈ is hydrogen or fluorine,
in which R₉ is hydrogen, (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy, halogen;
where (C₁-C₄)-alkyl may be substituted by (C₁-C₄)-alkoxy,
n represents 0 or 1,
m represents 0, 1 or 2,
p represents 0, 1 or 2 and
q represents 0, 1 or 2,
and the salts, solvates and solvates of the salts thereof.

- 4.2 D1-D2 disclose a series of compounds that fall within the scope of claim 1 (see details in search report).
- 4.3 D4, D5 and D7 disclose the subject-matter of claims 1-2.
- 4.4 D3 and D6 disclose the subject-matter of claims 1-5.
- 4.5 D1 also concerns bioactive compounds and more particularly discloses medical applications that overlap with the ones of the present application (see for instance respiratory distress syndrome as well as cardiac and neurodegenerative disorders). Therefore the subject-matter of medical application claims 12-21 is considered to be anticipated by D1.
- 4.6 As regard the compound claims 6-10, they concerns single compound formula that are not disclosed in the prior art.
- 4.7 As regard process claim 11, D1-D2 use the same process (see p.56-61) as detailed in [C] alternative method of said claim 11.
- 5 Inventive step (Art. 33(3)).
- 5.1 As regard the novel claims 6-10, they should be considered as inventive for the following reason.

- 5.2 The documents D3-D7 are chemical database abstracts, without any suggested medical application, therefore they are not relevant for inventive step.
- 5.3 D1-D2 disclose structurally close compounds but fail to disclose any activity as antagonist of alpha-2C adrenergic receptor, although some of the medical applications overlap with the presently claimed ones. Furthermore, none of the examples of D1-D2 comprises the bi-piperidine ending group of the present compounds of claims 6-10.
- 5.4 The closest prior art should be considered to be D8 which discloses compounds of general formula (I), which are alpha-2C adrenergic receptor antagonists:



The present compounds differ from the ones of D8 only by the absence of a carbonyl linker (highlighted above).

In the absence of any comparative example, the technical problem can be construed as the provision of alternative alpha-2C adrenergic receptor antagonists.

The solution represented by single compounds of claims 6-10 appears to convincingly solve said problem in view of the biological tests provided (see description pages 258-263).

There is no hint in the prior art that would have prompted the skilled person to modify the compounds of D8 to arrive to the present compounds. Therefore, given the structural differences between claims 6-10 and D8, it cannot be said with any degree of accuracy that the skilled person, faced with the problem of providing further novel compounds useful as alpha-2C adrenergic receptor antagonists would have been unambiguously led to prepare the compounds of the present application.

Re Item VII

Certain defects in the international application

- 1 The closest prior art D8 and D1 should be cited and briefly commented.

Re Item VIII

Certain observations on the international application

- 1 Claim 1 is not considered to be clear (Art. 6 PCT) for the following reason.
 - 1.1 In general formula (I), Z is not defined when Y is CR4 or NR4 and X is S. Claim 1 cannot be considered as fully defined which casts a doubt on its exact scope.

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submitted online

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Our Ref: 120983P1535PC EF/PT
Date: August 7, 2025

International Patent Application PCT/EP2024/077295
Bayer Aktiengesellschaft
SUBSTITUTED HETEROCYCLIC CARBOXAMIDES AND
USE THEREOF

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In reply to the invitation to submit amendments dated August 4,
2025:

We enclose a set of amended claims and request to base the
International Preliminary Examination on these claims.

1. Claim amendments

New claims 6 to 10 have been introduced.

The subject-matter of new claims 6 to 10 relates to specific
compounds encompassed by the original claims, in particular
original claims 1 to 5.

New claim 6 is supported by original claims 1 to 5 and Example 26 on pages 134 and 135 of the application as originally filed (reference is made to WO 2025/068514 A1).

New claim 7 is supported by original claims 1 to 5, Example 13 (page 128) and Example 29 on pages 137 to 139 of the application as originally filed. On page 139, line 6, it is disclosed that diastereomer 2 of Example 29 has positive optical rotation in methanol ($[\alpha]_D^{20} = +14.85^\circ$ ($c = 0.330$, methanol)).

New claim 8 is supported by original claims 1 to 5, Example 13 (page 128) and Example 28 on pages 137 and 138 of the application as originally filed. On page 138, line 19, it is disclosed that diastereomer 1 of Example 28 has negative optical rotation in methanol ($[\alpha]_D^{20} = -15.98^\circ$ ($c = 0.290$, methanol)).

New claim 9 is supported by original claims 1 to 5 and Example 25 (pages 133 and 134), Example 38 (page 143) and Example 65 (pages 159 and 160) of the application as originally filed. On page 160, line 6, it is disclosed that diastereomer 1 of Example 65 has positive optical rotation in methanol ($[\alpha]_D^{20} = +27.38^\circ$ ($c = 0.280$, methanol)).

New claim 10 is supported by original claims 1 to 5 and Example 25 (pages 133 and 134), Example 38 (page 143) and Example 66 (pages 159 and 160) of the application as originally filed. On page 160, line 20, it is disclosed that diastereomer 2 of Example 66 has negative optical rotation in methanol ($[\alpha]_D^{20} = -37.82^\circ$ ($c = 0.275$, methanol)).

In amended claims 12 to 21 (original claims 7 to 16), the dependencies of the claims have been adapted accordingly.

2. Conclusion

It is requested to base the International Preliminary Examination on the enclosed claim set.

- *signed electronically* -

Dr. Erich Fritsche
European Patent Attorney
(Association No. 809)

Enclosures

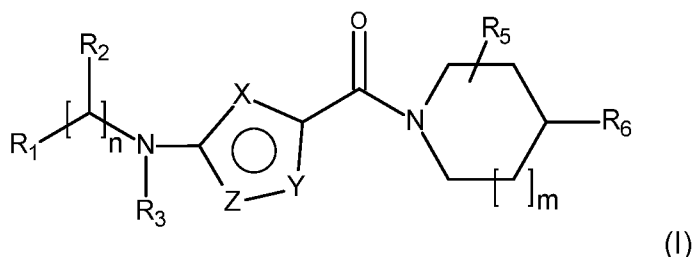
Amended claims 1 to 21 (marked-up and clean copies)

Amendments under Art. 34 PCT**Amended Claims**

(clean copy)

5

1. A compound of the general formula (I)



in which

X is S, N or O;

10

Z is N, S or O,

where, when X is S, Z is N;

where, when X is O, Z is N;

Y is CR₄, O or NR₄,

where, when X is N and Z is N, Y is O;

15

where, when X is S, Y is CR₄ or NR₄;

R₁ is 5- to 10-membered heteroaryl, phenyl, (C₄-C₁₀)-heterocycloalkyl or (C₃-C₁₀)-cycloalkyl,

in which 5- to 10-membered heteroaryl may be substituted by 1 to 3 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy, halogen;

20

where (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

where (C₁-C₄)-alkoxy may be up to trisubstituted by halogen,

in which phenyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₃-C₅)-cycloalkyl, (C₁-C₄)-alkoxy, cyano, hydroxy, halogen;

25

where (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₃-C₁₀)-cycloalkyl and (C₄-C₁₀)-heterocycloalkyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₃-C₅)-cycloalkyl, (C₁-C₄)-alkoxy, cyano, hydroxy, halogen;

5 where (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₃-C₁₀)-cycloalkyl and (C₄-C₁₀)-heterocycloalkyl may be fused to 5- to 10-membered heteroaryl,

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy and halogen;

10

R₂ is hydrogen, (C₁-C₄)-alkyl or (C₃-C₅)-cycloalkyl;

in which (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

in which (C₁-C₄)-alkyl may be substituted by cyano or (C₁-C₄)-alkoxy,

in which (C₃-C₅)-cycloalkyl may be up to trisubstituted by halogen,

15

or

together with the carbon atom to which R₂ is bonded forms a (C₃-C₄)-cycloalkyl ring,

or

R₁ and R₂ together form a (C₅-C₈)-cycloalkyl or (C₅-C₁₀)-heterocycloalkyl ring,

20 in which (C₅-C₈)-cycloalkyl may be fused to 5- to 10-membered heteroaryl,

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy and halogen;

in which (C₃-C₁₀)-heterocycloalkyl may be fused to 5- to 10-membered heteroaryl,

25

where 5- to 10-membered heteroaryl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy and halogen;

R₃ is hydrogen, (C₁-C₄)-alkyl,

in which (C₁-C₄)-alkyl may be up to trisubstituted by halogen,

R₄ in CR₄ is hydrogen, (C₁-C₄)-alkyl, (C₃-C₄)-cycloalkyl, phenyl, halogen;

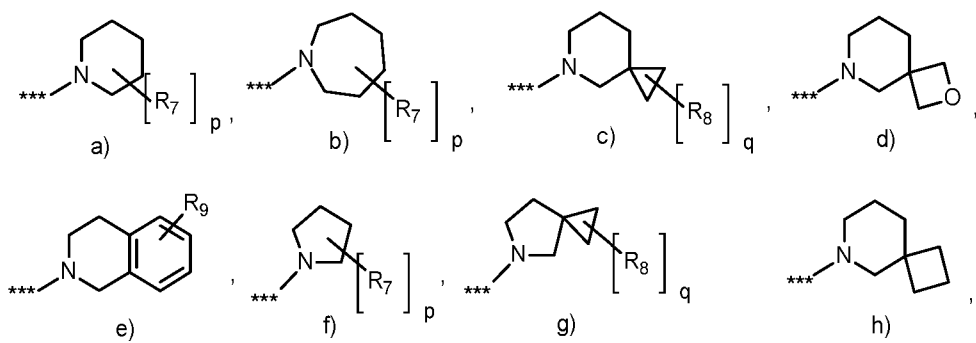
in which (C₁-C₄)-alkyl may be up to trisubstituted by halogen and phenyl
may be substituted by halogen,

in NR₄ is absent or is hydrogen, (C₁-C₄)-alkyl, (C₃-C₄)-cycloalkyl, phenyl;

in which (C₁-C₄)-alkyl may be up to trisubstituted by halogen and phenyl
may be substituted by halogen,

R₅ is hydrogen, (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy, halogen,

R₆ is a group of formula a), b), c), d), e), f) or g)



in which *** marks the attachment to the adjacent piperidine ring,

in which R₇ is hydrogen, (C₁-C₄)-alkyl, (C₃-C₄)-cycloalkyl, (C₁-C₄)-alkoxy,
(C₃-C₄)-cycloalkoxy, phenyl,

where (C₁-C₄)-alkyl may be substituted by (C₃-C₄)-cycloalkyl, (C₁-C₄)-alkoxy,
(C₃-C₄)-cycloalkoxy and up to trisubstituted by halogen,

where (C₁-C₄)-alkoxy may be substituted by (C₃-C₄)-cycloalkyl and up to trisubstituted by halogen,

where (C₃-C₄)-cycloalkyl may be substituted by monofluoromethyl, difluoromethyl or trifluoromethyl and up to disubstituted by halogen,

where (C₁-C₄)-alkoxy may be substituted by (C₃-C₄)-cycloalkyl and up to trisubstituted by halogen,

where (C₃-C₄)-cycloalkyl may be mono- or disubstituted
by halogen,

where (C₃-C₄)-cycloalkoxy may be up to disubstituted by halogen,

in which R₈ is hydrogen or fluorine,

in which R₉ is hydrogen, (C₁-C₄)-alkyl, (C₁-C₄)-alkoxy, halogen;

where (C₁-C₄)-alkyl may be substituted by (C₁-C₄)-alkoxy,

n represents 0 or 1,

m represents 0, 1 or 2,

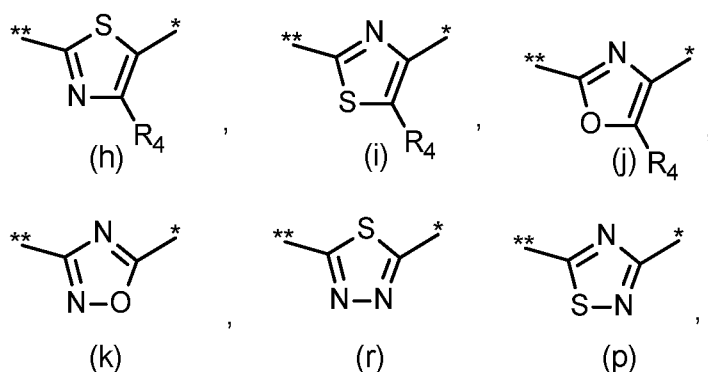
p represents 0, 1 or 2 and

q represents 0, 1 or 2,

or the salts, solvates or solvates of the salts thereof.

2. Compounds of the formula (I) according to Claim 1, in which

the aromatic 5-membered ring comprising X, Y and Z is chosen from the aromatic
5-membered rings having the structural formulae h), i), j), k), r) and
p),



in which * marks the attachment to the carbonyl group and ** the attachment to
the nitrogen atom of the adjacent amino group and

R₁ is pyridinyl, pyrazolyl, thiazolyl, thienyl, phenyl, tetrahydropyranyl or
cyclohexyl,

in which pyridinyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₂)-alkyl, fluorine, chlorine, trifluoromethyl, trifluoromethoxy,

in which pyrazolyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₂)-alkyl, fluorine, chlorine, trifluoromethyl,

in which thiazolyl may be substituted by chlorine,

in which thienyl may be substituted by fluorine,

in which phenyl may be substituted by 1 to 2 substituents selected independently from the group of (C₁-C₂)-alkyl, (C₃-C₄)-cycloalkyl, methoxy, cyano, hydroxy, fluorine, chlorine, trifluoromethyl,

in which cyclohexyl and tetrahydropyranyl may be fused to pyridyl,

R₂ is hydrogen, methyl,

in which methyl may be substituted by cyano or methoxy,

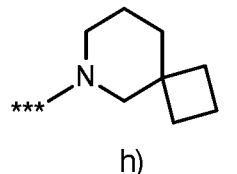
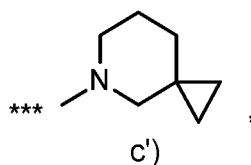
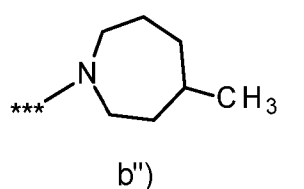
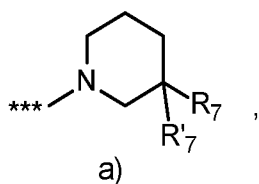
R₃ is hydrogen, (C₁-C₂)-alkyl;

R₄ is hydrogen, methyl, ethyl, cyclopropyl, trifluoromethyl, bromine, chlorine, phenyl;

where phenyl may be substituted by chlorine,

R₅ is hydrogen, fluorine;

R₆ is a group of the formula a), b''), c') or h),



in which *** marks the attachment to the adjacent piperidine ring,

in which R_7 or R'_7 is independently hydrogen, (C_1-C_4) -alkyl, (C_3-C_4) -cycloalkyl, (C_1-C_2) -alkoxy, (C_3-C_4) -cycloalkoxy, monofluoromethyl, difluoromethyl, trifluoromethyl, difluoromethoxy, phenyl,

where (C_1-C_4) -alkyl may be substituted by methoxy, n-butoxy, cyclopropyl, cyclobutoxy and up to disubstituted by fluorine,

where methoxy may be substituted by cyclopropyl, cyclobutyl, trifluoromethyl,

where cyclopropyl may be substituted by monofluoromethyl, difluoromethyl, trifluoromethyl,

where cyclopropyl may be up to disubstituted by fluorine,

where n-butoxy may be up to disubstituted by fluorine,

where (C_1-C_2) -alkoxy may be substituted by cyclopropyl, cyclobutyl, cyclobutoxy, trifluoromethyl and

where cyclopropyl and cyclobutyl may be up to disubstituted by fluorine,

where (C_3-C_4) -cycloalkoxy may be up to disubstituted by fluorine,

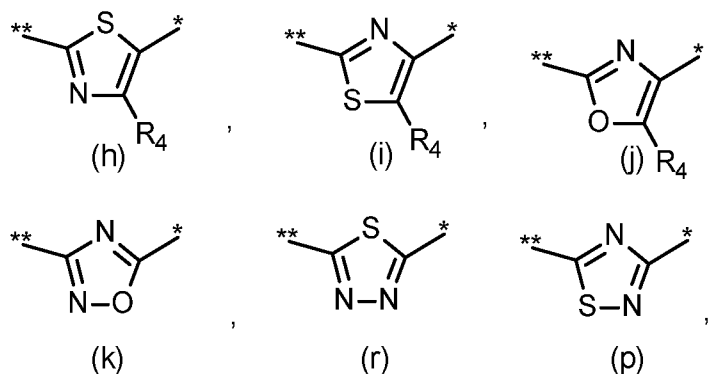
n represents 0 or 1 and

m represents 1 or 2,

or the salts, solvates or solvates of the salts thereof.

3. Compounds of the formula (I) according to Claim 1, in which

the aromatic 5-membered ring comprising X, Y and Z is chosen from the aromatic 5-membered rings having the structural formulae h), i), j), k), r) and p),



in which * marks the attachment to the carbonyl group and ** the attachment to the nitrogen atom of the adjacent amino group and

R₁ is pyridinyl, 2-ethylpyridinyl, 4,6-dimethylpyridinyl, 3,5-difluoropyridinyl, 3-fluoropyridinyl, 4-trifluoromethylpyridinyl, 6-trifluoromethylpyridinyl, 5-chloro-3-fluoropyridinyl, 3-chloro-5-fluoropyridinyl, 3-methylpyridinyl, 4-methylpyridinyl, 6-methylpyridinyl, 3-chloropyridinyl, 5-chloropyridinyl, 6-trifluoromethoxypyridinyl, phenyl, 2-methylphenyl, 3-methylphenyl, 4-methylphenyl, 3-methoxyphenyl, 4-trifluoromethylphenyl, 2-chlorophenyl, 3-chlorophenyl, 4-chlorophenyl, 2-fluorophenyl, 3-fluorophenyl, 4-fluorophenyl, 3-hydroxyphenyl, 2,5-difluorophenyl, 5-chloro-2-hydroxyphenyl, 5-fluoro-2-methoxyphenyl, 5-chloro-2-fluorophenyl, 2-chloro-5-fluorophenyl, 2-chloro-4-fluorophenyl, 3-cyano-4-fluorophenyl, 2-cyclopropylphenyl, 4-chloro-1-methyl-1H-pyrazolyl, 5-chloro-1,3-thiazolyl, 5-fluoro-2-thienyl;

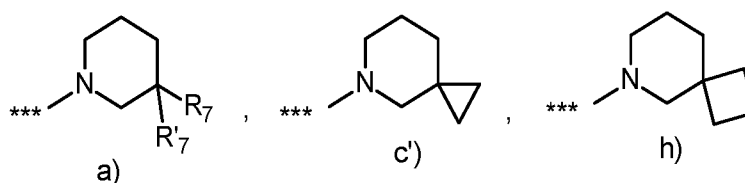
R₂ is hydrogen or methyl;

R₃ is hydrogen, methyl;

R₄ is hydrogen, ethyl or trifluoromethyl;

R₅ is hydrogen, methyl or fluorine;

R₆ is a group of the formula a), c') or h)



in which *** marks the attachment to the adjacent piperidine ring,

in which R₇ and R'₇ are independently hydrogen, methyl, ethyl, n-propyl, isopropyl, tert-butyl, 2-fluoroethyl, cyclopropyl, cyclobutyl, cyclopropylmethyl, methoxy, ethoxy, methoxymethyl, monofluoromethyl, difluoromethyl, trifluoromethyl, difluoromethoxy, 3,3-difluorocyclobutylmethoxy, cyclobutylmethoxy, cyclopropylmethoxy, cyclopropylmethoxymethyl, cyclobutyloxymethyl, 3-fluorobutyloxymethyl, 3,3-difluorocyclobutylmethoxymethyl, 2,2,2-trifluoroethoxy, 2,2,2-trifluoroethoxymethyl, 2,2-difluorocyclopropylmethoxy, cyclobutyloxy, 3,3-difluorocyclobutyloxy, fluoromethylcyclopropylmethoxy, difluoromethylcyclopropylmethoxy, trifluoromethylcyclopropylmethoxy, fluorine;

n represents 1 and

m represents 1,

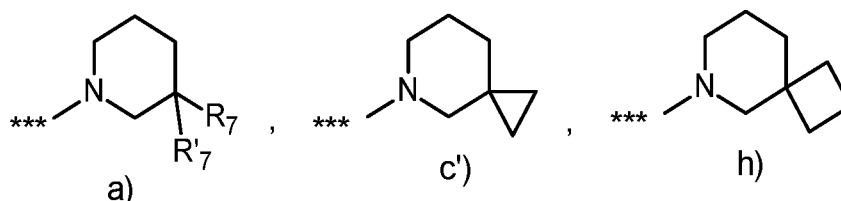
or the salts, solvates or solvates of the salts thereof.

4. Compounds of the formula (I) according to Claim 1, in which

the aromatic 5-membered ring comprising X, Y and Z is chosen from 1,3-thiazolyl, 1,3-oxazolyl, and 1,2,4-oxadiazolyl;

R₁ is pyridinyl, 2-ethylpyridinyl, 4,6-dimethylpyridinyl, 3,5-difluoropyridinyl, 3-fluoropyridinyl, 4-trifluoromethylpyridinyl, 6-trifluoromethylpyridinyl, 5-chloro-3-fluoropyridinyl, 3-chloro-5-fluoropyridinyl, 3-methylpyridinyl, 4-methylpyridinyl, 6-methylpyridinyl, 3-chloropyridinyl, 5-chloropyridinyl, 6-trifluoromethoxypyridinyl, phenyl, 2-methylphenyl, 3-methylphenyl, 4-methylphenyl, 3-methoxyphenyl, 4-trifluoromethylphenyl, 2-chlorophenyl, 3-chlorophenyl, 4-chlorophenyl, 2-fluorophenyl, 3-fluorophenyl, 4-fluorophenyl, 3-hydroxyphenyl, 2,5-difluorophenyl, 5-chloro-2-hydroxyphenyl, 5-fluoro-2-methoxyphenyl, 5-chloro-2-fluorophenyl, 2-chloro-5-fluorophenyl, 2-chloro-4-fluorophenyl, 3-cyano-4-fluorophenyl, 2-cyclopropylphenyl, 4-chloro-1-methyl-1H-pyrazolyl, 5-chloro-1,3-thiazolyl, 5-fluoro-2-thienyl;

- R₂ is hydrogen or methyl;
 R₃ is hydrogen, methyl;
 R₅ is hydrogen, methyl or fluorine;
 R₆ is a group of the formula a), or c') or h)



5

in which *** marks the attachment to the adjacent piperidine ring,

in which R₇ and R'₇ are independently hydrogen, methyl, ethyl, n-propyl, isopropyl, tert-butyl, 2-fluoroethyl, cyclopropyl, cyclobutyl, cyclopropylmethyl, methoxy, ethoxy, methoxymethyl, monofluoromethyl, difluoromethyl, trifluoromethyl, difluoromethoxy, 3,3-difluorocyclobutylmethoxy, cyclobutylmethoxy, cyclopropylmethoxy, cyclopropylmethoxymethyl, cyclobutyloxymethyl, 3-fluorobutyloxymethyl, 3,3-difluorocyclobutylmethoxymethyl, 2,2,2-trifluoroethoxy, 2,2,2-trifluoroethoxymethyl, 2,2-difluorocyclopropylmethoxy, cyclobutyloxy, 3,3-difluorocyclobutyloxy, fluoromethylcyclopropylmethoxy, difluoromethylcyclopropylmethoxy, trifluoromethylcyclopropylmethoxy, fluorine;

10

15

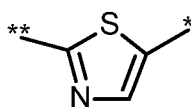
n represents 1 and

m represents 1,

20

or the salts, solvates or solvates of the salts thereof.

5. Compounds of the formula (I) according to Claim 1, in which the aromatic 5-membered ring comprising X, Y and Z is the aromatic 5-membered ring having the structural formula h'),



(h')

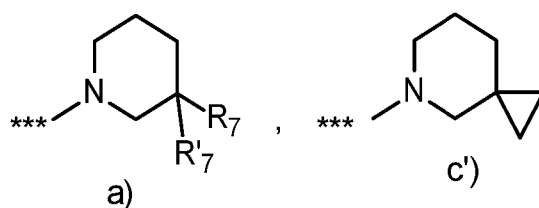
R₁ is pyridinyl, 2-ethylpyridinyl, 4,6-dimethylpyridinyl, 3,5-difluoropyridinyl, 3-fluoropyridinyl, 4-trifluoromethylpyridinyl, 6-trifluoromethylpyridinyl, 5-chloro-3-fluoropyridinyl, 3-chloro-5-fluoropyridinyl, 3-methylpyridinyl, 4-methylpyridinyl, 6-methylpyridinyl, 3-chloropyridinyl, 5-chloropyridinyl, 6-trifluoromethoxypyridinyl, phenyl, 2-methylphenyl, 3-methylphenyl, 4-methylphenyl, 3-methoxyphenyl, 4-trifluoromethylphenyl, 2-chlorophenyl, 3-chlorophenyl, 4-chlorophenyl, 2-fluorophenyl, 3-fluorophenyl, 4-fluorophenyl, 3-hydroxyphenyl, 2,5-difluorophenyl, 5-chloro-2-hydroxyphenyl, 5-fluoro-2-methoxyphenyl, 5-chloro-2-fluorophenyl, 2-chloro-5-fluorophenyl, 2-chloro-4-fluorophenyl, 3-cyano-4-fluorophenyl, 2-cyclopropylphenyl, 4-chloro-1-methyl-1H-pyrazolyl, 5-chloro-1,3-thiazolyl, 5-fluoro-2-thienyl;

R₂ is hydrogen or methyl;

R₃ is hydrogen or methyl;

R₅ is hydrogen, fluorine;

R₆ is a group of the formula a) or c')



in which *** marks the attachment to the adjacent piperidine ring,

in which R₇ and R'₇ are independently hydrogen, methyl, ethyl, n-propyl, isopropyl, tert-butyl, 2-fluoroethyl, cyclopropyl, cyclobutyl, cyclopropylmethyl, methoxy, ethoxy, methoxymethyl, monofluoromethyl, difluoromethyl, trifluoromethyl, difluoromethoxy, 3,3-difluorocyclobutylmethoxy, cyclobutylmethoxy, cyclopropylmethoxy,

cyclopropylmethoxymethyl, cyclobutyloxymethyl, 3-fluorobutyloxymethyl,
3,3-difluorocyclobutylmethoxymethyl, 2,2,2-trifluoroethoxy, 2,2,2-
trifluoroethoxymethyl, 2,2-difluorocyclopropylmethoxy, cyclobutyloxy, 3,3-
difluorocyclobutyloxy, fluoromethylcyclopropylmethoxy,
5 difluoromethylcyclopropylmethoxy, trifluoromethylcyclopropylmethoxy,
fluorine;

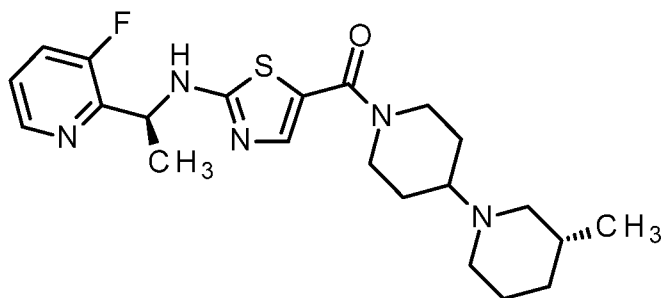
n represents 1 and

m represents 1,

or the salts, solvates or solvates of the salts thereof.

10

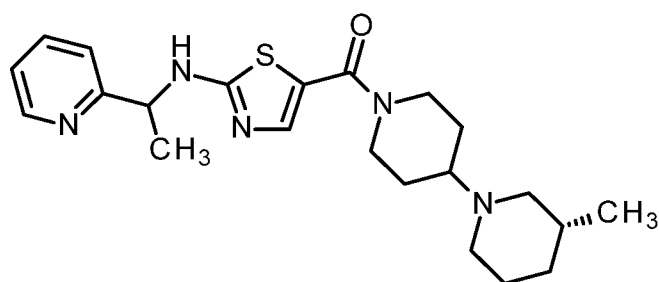
6. A compound represented by the following structural formula:



or a salt, solvate, or solvate of a salt thereof.

15

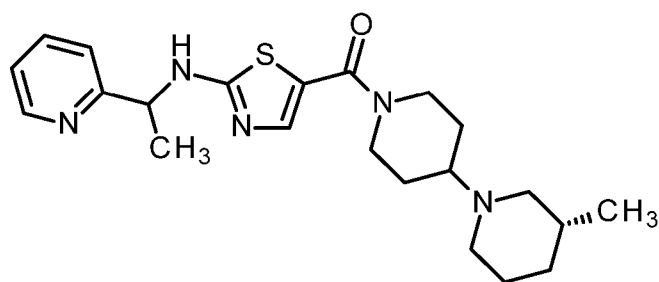
7. A compound represented by the following structural formula:



, or a salt, solvate, or solvate of a salt thereof, wherein the compound has positive optical rotation in methanol.

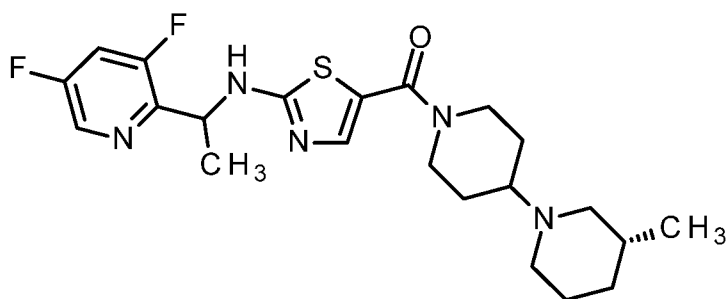
20

8. A compound represented by the following structural formula:



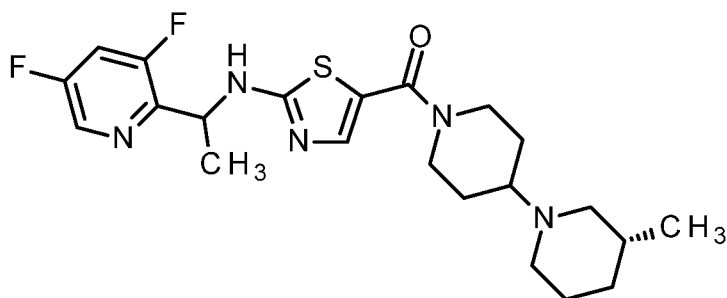
, or a salt, solvate, or solvate of a salt thereof, wherein the compound has negative optical rotation in methanol.

- 5 9. A compound represented by the following structural formula:



, or a salt, solvate, or solvate of a salt thereof, wherein the compound has positive optical rotation in methanol.

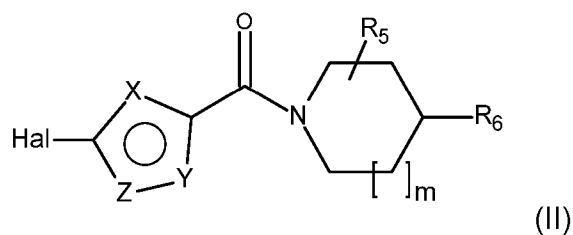
- 10 10. A compound represented by the following structural formula:



, or a salt, solvate, or solvate of a salt thereof, wherein the compound has negative optical rotation in methanol.

- 15 11. Process for preparing the compounds of the formula (I) or salts thereof, solvates thereof or solvates of the salts thereof, where

[A] compounds of the formula (II)

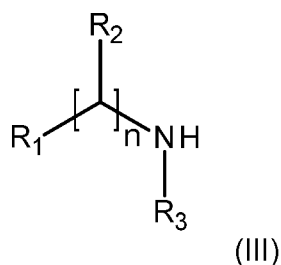


in which

X, Y, Z, R₅, R₆, and m have definitions given above,

Hal is a leaving group, preferably chlorine, bromine, iodine, or
methylsulfonyl,

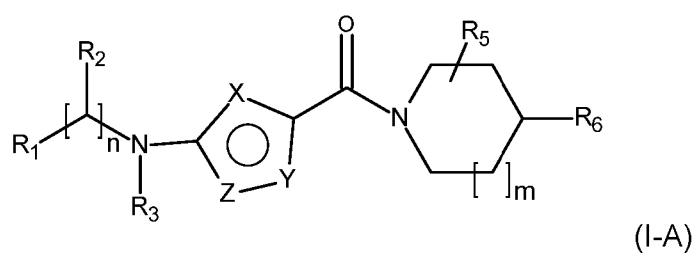
are reacted in the presence of a base with compounds of the formula (III)



in which

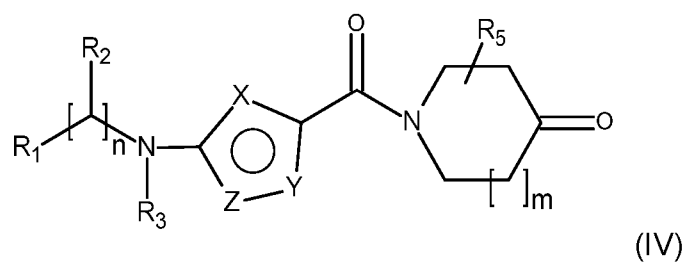
R₁, R₂ and R₃ and n have the definitions given above,

to give compounds of the formula (I-A)



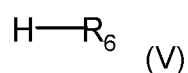
or

[B] compounds of the formula (IV)



in which

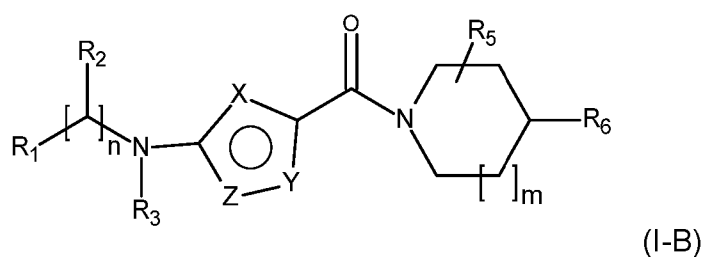
X, Y, Z, R₁, R₂, R₃, R₄ and R₅ and n and m have the definitions given above,
are reacted with compounds of the formula (V)



in which

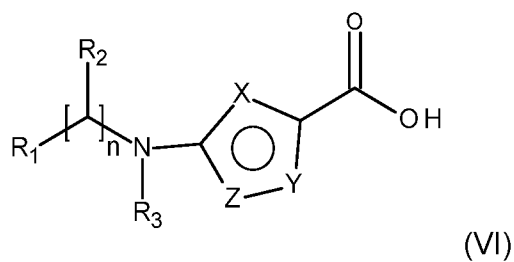
R₆ has the definition given above,

in the presence of a reducing agent and optionally an acid, preferably alkali metal borohydrides and acetic acid, to give compounds of the formula (I-B)



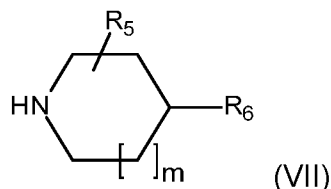
or

[C] compounds of the formula (VI)



in which

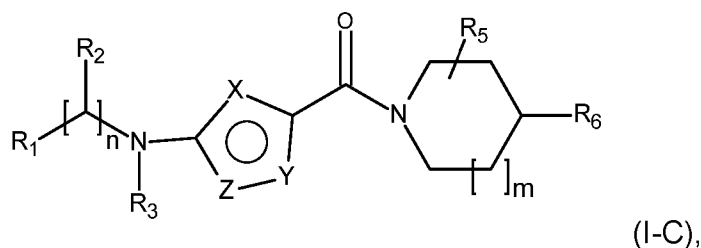
X, Y, Z, R₁, R₂ and R₃ and n have the definitions given above,
are reacted with compounds of the formula (VII)



in which

R₅ and R₆ and m have the definitions given above,

in the presence of a condensing or activating agent, preferably a phosphorus compound, to give compounds of the formula (I-C)



and the compounds of the formulae (I-A), (I-B), (I-C) thus obtained are optionally separated into their enantiomers and/or diastereomers and/or optionally converted with the appropriate (i) solvents and/or (ii) acids to the solvates, salts and/or solvates of the salts thereof.

12. Compound as defined in any of claims 1 to 10 for treatment and/or prevention of diseases.

13. Compound as defined in any of Claims 1 to 10 for use in a method for treatment and/or prevention of breathing difficulties, dysphagia, peripheral and cardiac vascular disorders and disorders of the peripheral and central nervous system.

14. Compound as defined in any of Claims 1 to 10 for use in a method for treatment and/or prevention of breathing difficulties including sleep-induced breathing difficulties such as central and obstructive sleep apnoea, snoring (primary and

obstructive snoring), dysphagia, peripheral and cardiac vascular disorders including diabetic microangiopathies and disorders of the peripheral and central nervous system including neurodegenerative and neuroinflammatory disorders.

5 15. Compound as defined in any of Claims 1 to 10 for use in a method for treatment and/or prevention of breathing difficulties including sleep-induced breathing difficulties such as, *inter alia*, obstructive sleep apnoea (in adults and children), primary snoring, obstructive snoring (upper airway resistance syndrome, heavy snoring, hypopnoea syndrome), central sleep apnoea, Cheyne-Stokes respiration,
10 primary sleep apnoea of infancy, apparent life-threatening event, central sleep apnoea as a result of the use of medicaments or the use of other substances, obesity hypoventilation syndrome, disrupted central respiratory drive, sudden infant death, primary alveolar hypoventilation syndrome, postoperative hypoxia and apnoea, muscular respiratory disorders, respiratory disorders following long-
15 term ventilation, respiratory disorders during adaptation in high mountains, acute and chronic pulmonary diseases with hypoxia and hypercapnia, sleep-related non-obstructive alveolar hypoventilation and the congenital central alveolar hypoventilation syndrome and dysphagia.

20 16. Compound as defined in any of Claims 1 to 10 for use in a method for treatment and/or prevention of peripheral and cardiac vascular disorders including diabetic microangiopathies, diabetic ulcers at the extremities, in particular for promoting wound healing of diabetic foot ulcers, diabetic heart failure, diabetic coronary microvascular cardiac disorders, peripheral and cardiac vascular disorders,
25 thromboembolic disorders and ischaemias, peripheral circulatory disorders, Raynaud's phenomenon, systemic scleroderma, CREST syndrome, microcirculation disorders and intermittent claudication.

17. Compound as defined in any of Claims 1 to 10 for use in a method for treatment
30 and/or prevention of disorders of the peripheral and central nervous system, including dementia, depression, schizophrenia, attention deficit disorder with or without hyperactivity (ADHS), Tourette's syndrome, post-traumatic stress disorder, obsessive-compulsive disorder, blepharospasm or other focal dystonias, drug-induced psychosis, temporal lobe epilepsy with psychosis, panic disorder,

disorders caused by changes in sexual hormones, multiple sclerosis, Alzheimer's disease, Parkinson's disease, Huntington's disease.

5 18. Medicament comprising a compound as defined in any of Claims 1 to 10 in combination with one or more inert, nontoxic, pharmaceutically suitable excipients.

10 19. Medicament, comprising a compound as defined in any of Claims 1 to 10 in combination with one or more further active compounds selected from the group consisting of respiratory stimulants, psychostimulating compounds, serotonin reuptake inhibitors, noradrenergic, serotonergic and tricyclic antidepressants, P2X3 antagonists, sGC stimulators, mineralocorticoid receptor antagonists, antiinflammatory drugs, immunomodulators, immunosuppressives and cytotoxic drugs.

15 20. Medicament according to Claim 18 or 19 for treatment and/or prevention of breathing difficulties, including sleep-induced breathing difficulties such as central and obstructive sleep apnoea, snoring (primary and obstructive snoring), dysphagia, peripheral and cardiac vascular disorders, including diabetic microangiopathies and disorders of the peripheral and central nervous system, including neurodegenerative and neuroinflammatory disorders.

20 21. Method for treatment and/or prevention of breathing difficulties including sleep-induced breathing difficulties such as central and obstructive sleep apnoea, snoring (primary and obstructive snoring), dysphagia, peripheral and cardiac vascular disorders including diabetic microangiopathies and disorders of the peripheral and central nervous system including neurodegenerative and neuroinflammatory disorders in humans and animals by administration of an effective amount of at least one compound as defined in any of Claims 1 to 10, or
25
30 of a medicament as defined in any of Claims 18 to 20.

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