

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

To:

see form PCT/ISA/220

## 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/EP2020/070547

International filing date (day/month/year)  
21.07.2020

Priority date (day/month/year)  
22.07.2019

International Patent Classification (IPC) or both national classification and IPC  
INV. C07D487/10 C07D487/08 C07D487/04 C07D471/10 C07D471/08 C07D401/14 C07D401/12 A61K31/497  
A61K31/444 A61K31/438 A61K31/407 A61P11/00 A61P29/00

Applicant  
BOEHRINGER INGELHEIM INTERNATIONAL GMBH

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:



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Date of completion of  
this opinion

see form  
PCT/ISA/210

Authorized Officer

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**Box No. I Basis of the opinion**

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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(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:
    - ☐ in the form of an Annex C/ST.25 text file.
    - ☐ on paper or in the form of an image file.
  - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
    - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
    - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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**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**

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1. Statement

|                               |             |             |
|-------------------------------|-------------|-------------|
| Novelty (N)                   | Yes: Claims | <u>1-10</u> |
|                               | No: Claims  |             |
| Inventive step (IS)           | Yes: Claims | <u>1-10</u> |
|                               | No: Claims  |             |
| Industrial applicability (IA) | Yes: Claims | <u>1-10</u> |
|                               | No: Claims  |             |

2. Citations and explanations

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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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 under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The following documents are cited in the present International Search Report:

D1            WO 2013/061297 A1 (PFIZER LTD [GB]) 2 May 2013 (2013-05-02)

**Novelty (Article 33(2) PCT)**

The present compounds differ from the compounds in D1 in the substituents -O-CH<sub>2</sub>-A and K.

The claimed matter is novel.

**Inventive Step (Article 33(3) PCT)**

D1 discloses 6-amino-pyridazin-3-yl carboxamide derivatives as autotaxin (ATX) modulators for the treatment of e.g. fibrotic diseases.

D1 is the closest prior art.

The problem of the invention was the provision of new autotaxin (ATX) modulators for the treatment of inflammatory airway or fibrotic diseases.

The present description discloses the preparation of exemplary compounds (e.g. pages 57 to 75; examples 1.1 to 5) as well as relevant biological data thereof (e.g. pages 15 to 21, tables 1 to 9).

The problem has been solved over the whole of the claimed scope.

D1 does not disclose or suggest any N-methyl, N-(6-(methoxy)pyridazin-3-yl) amine derivatives.

The claimed matter is based on an inventive step.

**Re Item VII**

**Certain defects in the international application**

**Description**

The relevant prior art D1 has not been cited in the description.

With entry into the regional phase before the EPO:

- If amended claims are filed, then the description has to be brought in line with the amended claim set at the same time. Please do not defer the adaptation of the description. This only results in an unnecessary delay in the granting procedure.
- The relevant prior art D1 cited in the present international search report must be cited in the description.
- A working copy (e.g. hand-amended version) wherein the amendments are visible as well as a readable, re-typed version (clear copy) as the print version must be filed at the same time, in order to avoid printing errors (hand-amended pages are not allowed for the print version).
- The basis for the amendments in the application as originally filed must be indicated.

### **Re Item VIII**

#### **Certain observations on the international application**

##### **Lack of Clarity (Article 6 PCT)**

With entry into the regional phase before the EPO the present claims 9 and 10 could be rephrased into "*The compound ... for use in a method of treatment or prevention of ...*".