

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43*bis*.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/IB2015/053975

International filing date (day/month/year)
27.05.2015

Priority date (day/month/year)
28.05.2014

International Patent Classification (IPC) or both national classification and IPC
INV. C07D487/04 A61K31/519 A61P29/00 A61P35/00 A61P37/00

Applicant
NOVARTIS AG

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 43*bis*.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 66.1*bis*(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
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

vanVoorsttotVoorst,M
Telephone No. +49 89 2399-0



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 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:

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

1. Statement

Novelty (N)	Yes: Claims	<u>1-15</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-15</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

RE ITEM V:

- 1 Claims 14 relateS to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT.
The patentability can also be dependent upon the formulation of the claims.
The EPO, for example, does not recognize 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.
- 2 The following document cited in the International Search Report is referred to in this communication.

D1 WO 2009/065897 A2 (VIB VZW [BE]; UNIV GENT [BE]; UNIV LEUVEN KATH [BE]; BEYAERT RUDI [BE]) 28 May 2009 (2009-05-28)cited in the application
- 3 D1 discloses certain compounds useful as MALT 1 inhibitors, the specific compounds disclosed on pages 22-28 of the description however bear no structural similarity with the compounds according to claim 1.
Therefore, the subject-matter as defined in claims 1-15 appears to meet the requirements of Article 33(2) PCT.
- 4 Closest prior art comprises the compounds disclosed in D1, which possess similar activities as the presently claimed compounds.
The problem to be solved was to provide further MALT 1 inhibitors, which can be used in the treatment of MALT 1-related diseases or disorders.
The Applicant has shown in the Biological Examples on pages 134-139 of the description that the present compounds are a solution to the problem defined above.
This solution also appears to involve an inventive step, since the skilled person, in view of the available prior art, could not have expected with any certainty that the compounds of formula would posses the desired activity.
Thus, the subject-matter of claims 1-15 appears to comply with the requirements of Article 33(3) PCT.

- 5 The term "in particular" used in claim 8 is not considered to satisfy Article 6 PCT.
- 6 No objections with regard to Article 33(4) PCT arise for present claims 1-15.