

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

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/EP2018/073965	International filing date (day/month/year) 06.09.2018	Priority date (day/month/year) 08.09.2017
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International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/19 A61K9/08 A61K47/02 A61K47/26

Applicant
BAYER PHARMA AKTIENGESELLSCHAFT

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:  European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Fax: +31 70 340 - 3016	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Muller, Sophie Telephone No. +31 70 340-0 
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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 43bis.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>2, 4, 6-9, 11-13, 15, 16, 18-21, 23-39, 41-45</u>
	No: Claims	<u>1, 3, 5, 10, 14, 17, 22, 40</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-45</u>
Industrial applicability (IA)	Yes: Claims	<u>1-45</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

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

1. Cited Document

The following document is referred to in this communication:

D1 WO 2017/134030 A1 (BAYER PHARMA AG [DE]) 10 August 2017
(2017-08-10)

2. Conciseness

Although claims 17 and 22 have been drafted as separate independent claims, they appear to relate to a similar subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3. Method of treatment

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 claims 38,40,41-45 has been assessed on the basis of a purpose-limited product claim taking into account the alleged effects of the substance or composition.

4. Novelty

D1 discloses (see page 87, line 5 - line 14 and page 89 - page 95) a sterile preparation prepared with a) 100-1000 mg of copanlisib hydrochloride as a lyophilized powder, b) 32-327 mg/mL sodium citrate as pH adjusting agent, and c) 300-3000 mg Dextran 40 as bulking agent. The formulation is reconstituted with sterile, injectable saline or dextrose 5%.

The subject-matter of claims 1,3,5,10,14,17,22,40 is therefore not new (Article 33(2) PCT).

5. Inventive Step

5.1. The subject-matter of claims 1,3,5,10,14,17,22,40 is not new and can therefore not involve an inventive step in the meaning of Article 33(3) PCT.

5.2. Present claims 2,4,6-9,11-13,15,16,18-21,23-39,41-45 are not considered to be inventive with respect to D1, insofar as they do not appear to comprise any technical features which lead to a non-obvious solution of a technical problem (Article 33(3) PCT).

6. Industrial applicability

Claims 1-45 satisfy the criterion of industrial applicability set forth in Article 33(4) PCT.