

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

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| To:                  |
| see form PCT/ISA/220 |

## 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<br>see form PCT/ISA/220                                                             |                                                          | <b>FOR FURTHER ACTION</b><br>See paragraph 2 below |
| International application No.<br>PCT/US2016/012124                                                                        | International filing date (day/month/year)<br>05.01.2016 | Priority date (day/month/year)<br>09.01.2015       |
| International Patent Classification (IPC) or both national classification and IPC<br>INV. C07K14/575 C07K14/605 A61K38/26 |                                                          |                                                    |
| Applicant<br>ELI LILLY AND COMPANY                                                                                        |                                                          |                                                    |

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:<br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | Date of completion of<br>this opinion<br><br>see form<br>PCT/ISA/210 | Authorized Officer<br><br>Chavanne, Franz<br><br>Telephone No. +49 89 2399-0 |
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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>1-19</u> |
|                               | No: Claims  |             |
| Inventive step (IS)           | Yes: Claims | <u>1-19</u> |
|                               | No: Claims  |             |
| Industrial applicability (IA) | Yes: Claims | <u>1-19</u> |
|                               | No: Claims  |             |

2. Citations and explanations

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

- 1        The claimed compound has been neither described nor suggested in the prior art. The subject-matter of claims 1-19 seems, thus, novel and inventive (Article 33(2)(3) PCT).

**Re Item VIII**

**Certain observations on the international application**

- 1        For the assessment of the present claims 15 and 16 on the question whether they are patentable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as patentable the subject-matter of claims to the use of a compound in medical treatment.
- 2        Claim 16 refers to a method. Claim 16 has been formulated as a dependent claim of claim 13. However, claim 13 is a product claim. It seems that claim 16 shall be formulated as a dependent claim of claim 15 (Article 6 PCT).
- 3        Claim 19 refers to the claimed compound of claims 1-13. Claim 19 further mentions that this compound is in simultaneous, separate or sequential combination with one or more agents. However, this does not correspond to technical features defining the compound itself but rather to indications concerning the therapeutic used thereof. It seems that claim 19 shall be formulated as dependent claim from independent claims 17 and 18 (Article 6 PCT).

**Information on Search Strategy - Pilot phase (see OJ 2015, A86)**

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

PCT/US2016/012124

TITLE: GIP AND GLP-1 CO-AGONIST COMPOUNDS

APPLICANT: ELI LILLY AND COMPANY

IPC CLASSIFICATION: C07K14/575, C07K14/605, A61K38/26

EXAMINER: Chavanne, Franz

CONSULTED DATABASES: BIOSIS, DOSYS, EMBASE, EPODOC, MEDLINE, NPL, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: C07K14/575, A61K38/26, C07K14/605

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

GIP/GLP-1 co-agonist. Shown in vitro binding and functional potency to both human GLP-1 and GIP receptors. Dose dependent increase of insulin secretion, for example after glucose injection. Low risk of clinical immunogenicity