**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

<table>
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<tr>
<th>Applicant’s or agent’s file reference</th>
<th>FOR FURTHER ACTION</th>
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<td>CWR-019171WO</td>
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<th>International application No.</th>
<th>International filing date (day/month/year)</th>
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International Patent Classification (8th edition unless older edition indicated)
See relevant information in Form PCT/ISA/237

Applicant
CASE WESTERN RESERVE UNIVERSITY

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1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - [x] Box No. I  Basis of the report
   - [ ] Box No. II  Priority
   - [x] 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

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**Date of issuance of this report**
12 June 2012 (12.06.2012)

**Authorized officer**
Nora Lindner
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The International Bureau of WIPO
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1211 Geneva 20, Switzerland
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Form PCT/IB/373 (January 2004)
PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
SUTKUS RICHARD A.
TAROLLI, SUNDHEIM, COVELL & TUMMINO LLP 1300 EAST NINTH STREET SUITE 1700 CLEVELAND OH 44114 USA

PCT
WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing (day/month/year) 18 AUGUST 2011 (18.08.2011)

Applicant's or agent's file reference CWR-019171WO FOR FURTHER ACTION See paragraph 2 below

International application No. International filing date (day/month/year) Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC
A61K 31/428(2006.01)i, A61K 31/4162(2006.01)i, A61K 31/4184(2006.01)i, A61K 31/56(2006.01)i, A61K 9/22(2006.01)i, A61K 9/20(2006.01)i, A61P 27/02(2006.01)i

Applicant CASE WESTERN RESERVE UNIVERSITY et al

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 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

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will 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.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 189 Cheongsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea
Facsimile No. 82-42-472-7140

Date of completion of this opinion 16 AUGUST 2011 (16.08.2011)
Authorized officer SUNG Sun Young
Telephone No 82-42-481-8405

Form PCT/ISA/237 (cover sheet) (July 2009)
Box No. 1  Basis of this 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. a sequence listing filed or furnished

☐ on paper
☒ in electronic form

 b. time of filing or furnishing

☐ contained in the international application as filed.
☒ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

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 in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:
Box No. III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☑ the entire international application
☐ claims Nos. ___________________________

because:

☑ the said international application, or the said claims Nos. 1-52, relate to the following subject matter which does not require an international search (specify):

The subject matter of claims 1-52 does not require an opinion with respect to industrial applicability as it is directed to a method of treatment of the human body (Rules 43 bis.1(b), Rule 67.1(iv)).

☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. ___________________________ are so unclear that no meaningful opinion could be formed (specify):

☐ the claims, or said claims Nos. ___________________________ are so inadequately supported by the description that no meaningful opinion could be formed (specify):

☑ no international search report has been established for said claims Nos. 1-52

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ See Supplemental Box for further details.