

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 770045CPCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/CN2017/086942	International filing date (<i>day/month/year</i>) 02 June 2017 (02.06.2017)	Priority date (<i>day/month/year</i>) 02 June 2016 (02.06.2016)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant INNOPHARMAX, INC.			

<p>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).</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>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.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>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).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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	Date of issuance of this report 04 December 2018 (04.12.2018)
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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 GE CHENG & CO.,LTD.

PCT

WRITTEN OPINION OF THE
 INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing <i>(day/month/year)</i> 13 September 2017	
Applicant's or agent's file reference 770045CPCT	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/CN2017/086942	International filing date <i>(day/month/year)</i> 02 June 2017
Priority date <i>(day/month/year)</i> 02 June 2016	
International Patent Classification (IPC) or both national classification and IPC A61K 9/107(2006.01)i; A61K 9/48(2006.01)i; A61K 31/7068(2006.01)i; A61P 35/00(2006.01)i	
Applicant INNOPHARMAX, INC.	

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 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/ STATE INTELLECTUAL PROPERTY OFFICE OF THE P.R.CHINA China 6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088	Date of completion of this opinion 30 August 2017	Authorized officer TIAN,Xiaoming
Facsimile No. (86—10) 62019451	Telephone No. (86-10)62411130	

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/CN2017/086942

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 43*bis*.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 filed or furnished:
 - a. (means)
 - on paper
 - in electronic form
 - b. (time)
 - in the international application as filed
 - together with the international application in electronic form
 - 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:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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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. 1-30

because:

the said international application, or the said claims Nos. 1-30 relate to the following subject matter which does not require an international search (*specify*):

[1] See the Form PCT/ISA/210 Box No. II.

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. _____

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.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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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

1. Statement

Novelty (N)	Claims	<u>14, 22, 30, 44, 49, 55</u>	YES
	Claims	<u>1-13, 15-21, 23-29, 31-43, 45-48, 50-54</u>	NO
Inventive step (IS)	Claims	<u>None</u>	YES
	Claims	<u>1-55</u>	NO
Industrial applicability (IA)	Claims	<u>1-55</u>	YES
	Claims	<u>None</u>	NO

2. Citations and explanations :

- [1] As mentioned in Box No. III, the opinion on the subject-matter of claims 1-30 is based on the alleged effects of the oral formulation.
- [2] Reference is made to the following documents:
- [3] D1: CN 102427803 B
- [4] D2: CN 104053438 A
- [5] D3: CN 101926779 A
- [6] D1 discloses an anti-tumor oral self micro-emulsifying pharmaceutical composition, which comprises gemcitabine hydrochloride 2%, glycerol 2.1%, PEG 400 30.2%, Tween 80 32.3%, Labrafil M1944 CS 13.4%, water 20%. The surfactant system exhibits a HLB value of 11.76. The dosage form is a hard or soft capsule (see embodiment 1).
- [7] D2 discloses the anticancer activity of gemcitabine on pancreatic cancer and bile duct cancer (see paragraph [0005]).
- [8] D3 discloses the anticancer activity of gemcitabine on breast cancer, bladder cancer, pancreatic cancer and non-small cell lung tumors (see paragraph [0004]).
- [9] Novelty:
- [10] Since D1 discloses the same GEMORAL preparation of the present application, the subject-matter of claims 1-13,15-21,23-29,31-43,45-48,50-54 is not regarded as novel in the light of D1. Claims 1-13,15-21,23-29,31-43,45-48,50-54 do not meet the requirement of Article 33(2) PCT.
- [11] Since D1-D3 do not disclose the subject-matter of claims 14,22,30,44,49,55, these claims meet the requirement of Article 33(2) PCT.
- [12] Inventive step:
- [13] The subject-matter of claims 1-13,15-21,23-29,31-43,45-48,50-54 does not involve an inventive step because it is not new. Therefore, claims 1-13,15-21,23-29,31-43,45-48,50-54 do not meet the requirement of Article 33(3) PCT.
- [14] The subject-matter of claim 14 differs from D1 in the kind of tumor. Since D2 discloses gemcitabine can treat pancreatic and bile duct cancer, or D3 discloses gemcitabine can treat breast, bladder, pancreatic and non-small cell lung tumors, the skilled person in the art can obtain the subject-matter of claim 14. Therefore, claim 14 does not involve an inventive step under Article 33(3) PCT. As the same reason, claims 22,30,44,49,55 do not involve an inventive step under Article 33(3) PCT.
- [15] Industrial applicability:
- [16] The invention of claims 1-55 can find industrial applicability in the technical field of pharmacy, thus meet the requirement of PCT Article 33(4).