

PATENT COOPERATION TREATY
From the **INTERNATIONAL SEARCHING AUTHORITY**

PCT

**WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY**

(PCT Rule 43 *bis*.1)

To: 510095 Suite 918-920 9/F, Dong Shan Plaza, No.69 Xianlie Central Road, Guangzhou 510095 P.R.CHINA ADVANCE CHINA I.P. LAW OFFICE

Date of mailing (day/month/year) 22 Oct. 2009 (22.10.2009)

Applicant's or agent's file reference PI09F115-PCT	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/CN2009/072789	International filing date(day/month/year) 16 Jul. 2009(16.07.2009)	Priority date (day/month/year) 16 Jul. 2008(16.07.2008)
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International Patent Classification (IPC) or both national classification and IPC C12Q1/68(2006.01)i

Applicant SHENZHEN CHINA GENE TECHNOLOGIES COMPANY, LTD. et al.
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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 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 66.1*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.

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

Name and mailing address of the ISA/CN The State Intellectual Property Office, the P.R.China 6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China 100088 Facsimile No. 86-10-62019451	Date of completion of this opinion 12 Oct. 2009 (12.10.2009)	Authorized officer ZHOU, Yang Telephone No. (86-10)62411041
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/CN2009/072789

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. a sequence listing filed or furnished
 - on paper
 - in electronic form
 - b. time of filing or furnishing
 - contained in the applicant as filed
 - filed together with the 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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CN2009/072789

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)	Claims <u>2-20</u>	YES
	Claims <u>1</u>	NO
Inventive step (IS)	Claims <u></u>	YES
	Claims <u>1-20</u>	NO
Industrial applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u></u>	NO

2. Citations and explanations

D1 (US2003148344 A1) discloses the method and apparatus for sequencing nucleic acid, wherein the said apparatus comprises: (a) a reagent delivery chamber wherein the chamber includes a substrate with immobilized nucleic acid; (b) a conduit in communication with the reagent delivery chamber; (c) an imaging system in communication with the reagent delivery chamber; and (d) a data collection system in communication with the imaging system (see claims 74-83, 84-87). D2 (US2003039978 A1) also discloses the method and apparatus for sequencing nucleic acid, wherein the said apparatus comprises: (a) an input chamber, (b) a microchannel in fluid communication with the input chamber, and (c) a detection unit operably coupled to the microchannel (see claims 18-26).

Novelty:

Claim 1 relates to a DNA sequencing reaction unit, which comprises: (a) a sequencing reaction chamber wherein the chamber includes an inner wall with immobilized DNA fragments; and (b) a reagent entrance and exit which applies for the reagent influx and efflux from the reaction chamber. Apparently, an apparatus substantially equal to the DNA sequencing reaction unit of claim 1 is inherent disclosed by D1 or D2. Therefore according to the disclosure of D1 or D2, the subject matter of claim 1 cannot be considered novel in the sense of Article 33(2) PCT.

Inventive step:

Claims 7-8 relate to a DNA sequencing reaction platform, which comprises a sequencing reaction unit, a temperature regulation unit, and a reagent control unit. It is obvious to the person skilled in the art that a temperature regulation unit and a reagent control unit are applied to a sequencing reaction unit based on the teaching of the primer intension sequencing method in D1. Therefore according to the teaching of D1, claims 7-8 cannot be considered as involving an inventive step in the sense of Article 33(3) PCT.

Claims 12-13 relate to a DNA sequencing reaction system, which comprises a sequencing reaction unit, an imaging unit, a data collection unit, and a control unit. D1 explicitly discloses that an imaging unit, a data collection unit, and a control unit are applied to a sequencing reaction unit. Therefore according to the teaching of D1, claims 12-13 cannot be considered as involving an inventive step in the sense of Article 33(3) PCT.

Claims 2-6, 9-11, 14-20 respectively relate to a DNA sequencing reaction unit, a DNA sequencing reaction platform, and a DNA sequencing reaction system, which further define the specific inner structure. However, the said specific inner structure is a common knowledge in the machinery art. Therefore, claims 2-6, 9-11, 14-20 cannot be considered as involving an inventive step in the case of claims 1, 7-8, 12-13 lacking of novelty or inventive step in the sense of Article 33(3) PCT.

Industrial applicability:

The DNA sequencing reaction unit, the DNA sequencing reaction platform, and the DNA sequencing reaction system respectively proposed in claims 1-20 can be made or used in an industry. Accordingly, the subject matters of claims 1-20 are considered industrially applicable and comply with the requirement of Article 33(4) PCT.