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No. 07-043820- -00003-0000

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Act. 329 CTOINFORMACION Folios: 11

Trámite : 011
Evento : 379
Actuación : 329

Referencia : Expediente No. 07043820
Asunto : SOLICITUD DE PATENTE PARA:
"AGENTES DE TRANSPORTE DERIVADOS DE CUPREDOXINAS Y
MÉTODOS DE UTILIZAR LOS MISMOS"
Solicitante : CHAKRABARTY AMANDA; DAS GUPTA TAPAS; YAMADA TOHRU;
FIALHO ARSENIO
Clase : C07K 014/195
Fecha de solicitud : Mayo 3 de 2007

1. Yo, Emilio FERRERO, obrando como apoderado del solicitante en el asunto de la referencia, presento junto con este escrito copia del Reporte de Examen Preliminar Internacional expedido en el trámite de la solicitud internacional PCT/US05/35758, en el cual se concluyó que la invención goza de novedad, nivel inventivo y aplicabilidad industrial.

2. Teniendo en cuenta que la presente solicitud se encuentra completa, solicito a ese Despacho proceda con la correspondiente publicación en la Gaceta de la Propiedad Industrial.

Señora Jefe,

EMILIO FERRERO
T.P.A. No. 31.929

COLO-15887-841-001-4
LMA\LMA\ID-147362\WPC15887
No. M-2009-147362\LMA

PATENT COOPERATION TREATY

(2) JCC 236

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DON PELTO
SHEPPARD MULLIN RICHTER & HAMPTON LLP
1300 I STREET NW
11TH FLOOR EAST
WASHINGTON, DC 20005

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing (day/month/year)	
Applicant's or agent's file reference 51282-00010	IMPORTANT NOTIFICATION
International application No. PCT/US05/35758	International filing date (day/month/year) 06 October 2005 (06.10.2005)
Priority date (day/month/year) 07 October 2004 (07.10.2004)	
Applicant CHAKRABARTY, ANANDA	

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
- REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Rodney P. Swartz, Ph.D. Telephone No. 571-272-1600
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Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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SHEPPARD MULLIN RICHTER & HAMPTON LLP
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(day/month/year) 20 MAR 2009

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Mail Stop PCT, Attn: IPEA/US
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Authorized officer

Rodney P. Swartz
Telephone No. 571-272-1600

Form PCT/IPEA/416 (January 2004)

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PATENT COOPERATION TREATY

PCT

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

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 51282-00010		FOR FURTHER ACTION		See Form PCT/IPEA/416																
International application No. PCT/US05/35758		International filing date (day/month/year) 06 October 2005 (06.10.2005)	Priority date (day/month/year) 07 October 2004 (07.10.2004)																	
International Patent Classification (IPC) or national classification and IPC IPC: Please See Continuation Sheet USPC: 424/9.1.9.2, 184.1, 185.1, 190.1, 192.1, 234.1, 250.1, 253.1, 260.1, 530/300, 350, 536/23.1, 23.7																				
Applicant CHAKRABARTY, ANANDA																				
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>9</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☐ (sent to the applicant and to the International Bureau) a total of <u>0</u> sheets, as follows: ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). 4. This report contains indications relating to the following items: <table border="0" style="width: 100%;"> <tr> <td>☒ Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td>☐ Box No. II</td> <td>Priority</td> </tr> <tr> <td>☐ Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐ Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <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>☐ Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☒ Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☒ Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>					☒ Box No. I	Basis of the report	☐ 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 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
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Date of submission of the demand <u>04 MAY 06</u>		Date of completion of this report <u>09 MARCH 09</u>																		
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/35758

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ 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 (under Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed inventions.

Claims 1-36 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: throughout the entire disclosure, bacterial names are in two forms, italics and not italics. For consistency, one form should be utilized.

Figure 2a is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof: the sequences shown are not clear, i.e., no individual residues can be discerned.

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/35758

Box No. VIII Certain observations on the international application

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:

Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/35758

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

a. type of material

- ☒ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☒ on paper
☒ in electronic form

c. time of filing/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 and/or examination
☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto 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.

3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US05/35758

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Continuation of IPC:
A61K 49/00(2006.01),39/00(2006.01),39/38(2006.01),39/02(2006.01),39/095(2006.01),39/10(2006.01),39/108(2006.01),38/00(2006.01);C07K 1/00(2006.01);C07H 21/02(2006.01),21/04(2006.01)

VIII. The following observations on the clarity of the claims, description, and drawings or on the questions, are made:
Claim 3 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 3 is indefinite for the following reason(s): The claim is drawn to a peptide which is "derived" from a microorganism. The disclosure does not define "derived" and therefore the metes and bounds of what constitutes such a "derivation" is unclear.

Claims 6, 7, and 8 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 6, 7, and 8 are indefinite for the following reason(s): Each of the claims list SEQ ID NO:47 twice as a choice from the listed group. Explanation is required.

Claims 1-3,5, and 9-36 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): The clams are drawn to peptides, complexes, and methods which are drawn to a peptide which has $\geq 90\%$ identity to a reference cupredoxin or H.8 outer membrane protein. However, the reference polypeptides are not indicated by any particular sequence listing. Therefore, the claims are indefinite because one cannot determine the metes and bounds of the claimed sequence because the reference is an unknown sequence.

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Supplemental Box

Claims 10 and 36 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): The claims are drawn to an isolated peptide which has "significant" structural homology to the 50-77 amino acid region of *P. aeruginosa*. It is unclear what are the metes and bounds of "significant" structural homology because the disclosure does not define the term.

Claims 13 and 14 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 13 and 14 are indefinite for the following reason(s): The claims are drawn to a cargo compound selected from the group comprising a protein, polypeptide, and a peptide. The disclosure, page 17, line 30 to page 18, line 17 defines the terms "polypeptide", "peptide", and "protein" as being interchangeable. Therefore, it is unclear what is meant in the claims by the use of all of the terms, while the description defines them as being one and the same.

Claim 20 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 20 is indefinite for the following reason(s): Claim 20 is drawn to a method comprising contacting a cell or cells with the complex of claim 11. The claim does not designate what type of cells are being contacted.

Claims 20-26 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 20-26 are indefinite for the following reason(s): The claims are drawn to contacting cells or treating a patient with cancer with the complex of claim 11. Claim 11 is a complex of an entry peptide and a cargo compound. It is unclear what treatment is being performed because claim 11 merely lists a "cargo" compound with no designation of what the cargo compound is. In addition, it is unclear how the complex distinguishes between normal cells and cancer cells.

Claims 27-31 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 27-31 are indefinite for the following reason(s): The claims are drawn to a method for diagnosing/imaging cancer, where "a cell" is contacted with the complex of claim 17 and the location of the cargo molecule is detected. It is unclear how one distinguishes between normal cells and cancer cells with the complex of claim 17.

Claims 1-9 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 1-9 are indefinite for the following reason(s): Claim 1 is directed to an isolated peptide consisting of a sequence that has at least 90% amino acid identity to less than a full-length wild-type cupredoxin or H.8 outer membrane protein, and which facilitates the entry of a linked molecule into a mammalian cancer cell.

Claim 1 contains no actual reference sequence identified by SEQ ID NO:. In addition, the disclosure has not provided sufficient information/guidance to determine which 10% identity can be lost without negating entry facilitation. Therefore, without an actual reference sequence (SEQ ID NO:) nor identity of the critical sequence(s) required to maintain entry activity, the claim is indefinite for the identity of the claimed peptide. Claims 2-9 depend from claim 1, but do not clarify the issues.