

Clarke, Modet & C^o

COLOMBIA

SEÑORES
DIVISIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
E. S. D.

REF: EXPEDIENTE No. 05107300
FECHA DE LA SOLICITUD: Octubre 21, 2005
SOLICITANTE: CENTRO DE INMUNOLOGÍA MOLECULAR
TITULO: ANTICUERPOS RECOMBINANTES Y FRAGMENTOS
QUE RECONOCEN EL GANGLIOSIDO N-GLICOLIL GM3 Y SU
USO PARA DIAGNOSTICO Y TRATAMIENTO

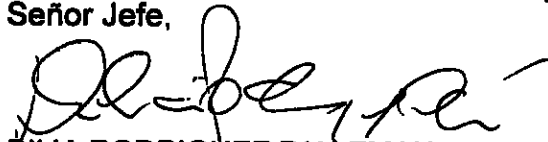
ASUNTO: COMPLEMENTO DE INFORMACION

DILIA RODRIGUEZ D'ALEMAN, en mi condición de apoderada de la
sociedad solicitante, por el presente escrito me permito anexar:

- Reporte de Búsqueda Internacional de la solicitud de la
referencia.
- Opinión Escrita.

Ruego a usted continuar con el presente trámite.

Señor Jefe,



DILIA RODRIGUEZ D'ALEMAN
C.C. 41.654.882 Bogota
T.P. 20824 CSJ

P-699

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference clm	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/CU 2004/000006	(Earliest) Priority Date (day/month/year) 23 April 2003 (23.04.2003)	International filing date (day/month/year) 22 April 2004 (22.04.2004)
Applicant CENTRO DE INMUNOLOGIA MOLECULAR		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☒ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see continuation of this first sheet

2. ☒ Certain claims were found unsearchable (see continuation of this first sheet)

3. ☐ Unity of invention is lacking (see continuation of this first sheet)

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in the continuation of this first sheet. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CU 2004/000006

Continuation of first sheet

Continuation No. I:

Nucleotide and/or amino acid sequence(s)

(Continuation of item 1.b of the first sheet)

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

b. format of material: in computer readable form

Continuation No. II:

Observations where certain claims were found unsearchable

(Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

Claims Nos.: 21, 22 because they relate to subject matter not required to be searched by this Authority, namely:

Remark: Although claims 21 and 22 concern the treatment of the human or animal body by therapy or a method of diagnosis practised on the human or animal body (see PCT Rule 39.1 (iv)) the search was carried out and based on the alleged effects.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CU 2004/000006

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
A			none	
EP	A	972782	none	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CU 2004/000006

A. CLASSIFICATION OF SUBJECT MATTER

C07K 16/46, A61K 39/395

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C07K 16/46, A61K 39/395

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CAS, Medline, STN-registry

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	EP 0972782 B1 (CENTRO DE INMUNOLOGIA MOLECULAR CIUDAD HABANA) 17 September 2003 (17.09.2003) <i>claims.</i>	5, 6, 13, 18, 20, 22, 25, 26
Y	EP 1013761 A2 (KYOWA HAKKO KOGYO CO., LTD) 18 September 1992 (18.09.1992) <i>claims.</i>	5, 6, 13, 18, 20, 22, 25, 26

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date or another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search
14 July 2004 (14.07.2004)Date of mailing of the international search report
30 August 2004 (30.08.2004)Name and mailing address of the ISA/ AT
Austrian Patent Office
Dresdner Straße 87, A-1200 ViennaAuthorized officer
MOSSER R.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/CU 2004/000006

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	MARQUINA, G et al Gangliosides expressed in human breast cancer Cancer research, 1995, Vol 56, No. 22, pages 5165-5172, Medline-abstract [online], [retrieved on 14 July 2004 (14.07.2004)]. Retrieved from EPOQUE Medline Database, AN NLM8912852 abstract	1-5, 19-26

PATENT COOPERATION TREATY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

ACOSTA MARTINEZ, Ada
Av. 1ra # 1001 esq. 10, Miramar, Playa,
Ciudad de la Habana, CubaDate of mailing 30 August 2004 (30.08.2004)
(day/month/year)Applicant's or agent's file reference
cimFOR FURTHER ACTION
See paragraph 2 belowInternational application No.
PCT/CU 2004/000006International filing date (day/month/year)
22 April 2004 (22.04.2004)Priority Date (day/month/year)
23 April 2003 (23.04.2003)International Patent Classification (IPC) or both national classification and IPC
C07K 16/46, A61K 39/395

Applicant

CENTRO DE INMUNOLOGIA MOLECULAR

1. This opinion contains indications relating to the following items:

- ☒ Cont. No. I Basis of the opinion
- ☐ Cont. No. II Priority
- ☐ Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Cont. No. IV Lack of unity of invention
- ☒ Cont. 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
- ☐ Cont. No. VI Certain documents cited
- ☐ Cont. No. VII Certain defects in the international application
- ☐ Cont. 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/ AT
Austrian Patent Office
Dresdner Straße 87, A-1200 Vienna

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Authorized officer

MOSSER R.

Telephone No. +43 / 1 / 534 24 / 437

60
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Continuation 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

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion was carried out on the basis of

b format of material in computer readable form

Continuation 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 1-26	YES
	Claims ----	NO
Inventive step (IS)	Claims 1-4, 7-12, 14-17, 19, 21-24	YES
	Claims 5, 6, 13, 18, 20, 22, 25, 26	NO
Industrial applicability (IA)	Claims 1-20, 23-26	YES
	Claims 21, 22	NO

2 Citations and explanations

EP 0972782 B1 concerns the murine 14F7 monoclonal antibody produced by the hybridoma with the deposit ECACC 98101901. The present application concerns humanized antibodies derived from said 14F7 monoclonal antibody.

EP 1013761 A2 relates to a humanized chimera antibody comprising a variable region of a mouse monoclonal antibody which is reactive with ganglioside and a human antibody constant region.

A person skilled in the art knows that humanized murine antibodies are less toxic for humans than animal antibodies. EP 1013761 A2 shows methods for the production of hybrid antibodies. Therefore it is obvious that elements from murine and human antibodies can be combined to create new pharmaceutical tools, especially for the identification of tumor

associated antigens and treatment of tumor cells. Accordingly, the subjects matters of claims 5, 6, 13, 18, 20, 22, 25, 26 are obvious from the above mentioned patent documents.

With sequence databases it can be shown that the sequences respectively the sequence combinations together with the 14 F7 antibody are new. A skilled person does not know which combinations will be the best. Further, it is difficult to find suitable expression systems for the production of chimeric antibodies. However, the examples of the application demonstrate the inventive step of the application. Therefore, novelty and inventive step are recognized for the subject matters of claims 1-4, 7-12, 14-17, 19 and 21-24.

Cancer research, 1995, Vol. 56, No. 22, pages 5165-5172 reveals that unusual gangliosides expressed in tumors may provide the basis for immunological diagnosis and vaccine therapy. But the murine 14F7 monoclonal antibody and derivatives thereof are not obvious from this document. Claims 21 and 22 concern the treatment of the human or animal body by therapy (see PCT Rule 39.1 (iv)). Therefore, industrial applicability is not given for these claims. The industrial applicability for the subject-matters of claims 1-20 and 23-26 is self-evident.