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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 06-077165- -00005-0000
Fecha: 2009-11-04 16:19:57 Dep: 2020 NUECREACIONI
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 329 CTOINFORMACION Folios: 14

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Señora Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

Trámite : 011 Evento : 379 Actuación : 329

Referencia : Expediente No. 06077165
Asunto : Solicitud de patente para **ANTICUERPOS CONTRA MADCAM**
Solicitante : PFIZER INC AND AMGEN FREMONT INC
Clase : A61K 048/000, A61K 049/000, C07K 016/030, C12N 005/012
Fecha de presentación: 4 de agosto de 2006.

1. Yo, LUZ CLEMENCIA DE PAEZ, obrando como apoderada de los solicitantes en el asunto antes identificado de acuerdo con las sustituciones de poder otorgadas a mi favor por Emilio FERRERO, me permito presentar adjunto a este escrito el Informe de Búsqueda Internacional (ISR) y la Opinión Escrita corregidos expedidos por la ISA en Agosto 6 de 2009 para la solicitud PCT/US2005/000370.

2. ANEXOS:
2.1 Informe de Búsqueda Internacional y Opinión Escrita corregidos.
2.2 Dos copias auténticas de las sustituciones de Poder otorgadas por Emilio Ferrero a mi favor.

Bogotá,
Señora Jefe,

LUZ CLEMENCIA DE PAEZ
T.P.A. No. 23.555

COLO-15413-841-001-9
AMG\AMG\ID-160561\WPC15413
No. M-2009-160561\AMG

894

Reviewed & Docketed

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
JAMES F. HALEY JR.
C/O FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

RECEIVED
AUG 10 2009
ROPES & GRAY LLP - IP DOCKETING
RECEIVED IN NY
FILED IN NY

PCT

COMMUNICATION IN CASES FOR WHICH NO OTHER FORM IS APPLICABLE

Applicant's or agent's file reference ABX-PF/6 PCT	Date of mailing (*day/month/year*) 06 AUG 2009 REPLY DUE See paragraph 1 below
International application No. PCT/US05/00370	International filing date (*day/month/year*) 07 January 2005 (07.01.2005)
Applicant AMGEN FREMONT, INC.	

1. ☐ REPLY DUE within _____ months/days from the above date of mailing

☒ NO REPLY DUE

2. COMMUNICATION:
The International Search Report and Written Opinion did not include claims 8-15,42 and 43. A corrected International Search Report and Written Opinion is hereby attached.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer SHIAN T. LUONG Telephone No. 571-272-4300

Form PCT/ISA/224 (January 1994; reprint January 2004)

595

Reviewed & Docketed

RECEIVED

AUG 10 2009

ROPES & GRAY LLP - IP DOCKETING
RECEIVED IN NY
FILED IN NY

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
JAMES F. HALEY JR.
C/O FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing (*day/month/year*) 06 AUG 2009
Applicant's or agent's file reference ABX-PF/6 PCT	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US05/00370	International filing date (*day/month/year*) 07 January 2005 (07.01.2005)
Applicant AMGEN FREMONT, INC	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

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

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ABX-PF/6 PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US05/00370	International filing date (*day/month/year*) 07 January 2005 (07.01.2005)	(Earliest) Priority Date (*day/month/year*) 09 January 2004 (09.01.2004)
Applicant AMGEN FREMONT, INC		

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.
      ☐ 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))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 Rule 43.6 *bis(a)*
   c. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☒ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
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 Box No. IV. 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/US05/00370

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out 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

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table 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:

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/00370

Box 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:

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 16-33,37-41,44-50
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/00370

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61K 48/00**(2006.01),**49/00**(2006.01);**C07K 16/30**(2006.01);**C12N 5/12**(2006.01)

USPC: 424/9.1,142.1;514/44;530/388.15,809;435/328
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)
U.S. : 424/9.1, 142.1; 514/44; 530/388.15, 809; 435/328

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)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	2001/0046496 (BRETTMAN et al.) 29 November 2001, see entor document.	1,2,35,36
---		---
Y		3,7,34,51-53
Y	US 2002/0065220 A1 (YOUNG et al.) 30 May 2002, see entire document.	34

☐ 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 published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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	Date of mailing of the international search report
05 August 2009 (05.08.2009)	06 AUG 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Ron Schwadron, Ph.D. Telephone No. 571 272 1600

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/00370

Continuation of B. FIELDS SEARCHED Item 3:
WEST, MEDICINE/BIOTECH (DIALOG) SEARCH TERMS: INVENTOR NAMES, MADCAM, HUMAN, ANTIBOD?, ECACC, XENOMOUSE, TRANSGEN?, MOUSE, ANTIMADCAM, GENE THERAP?, NUCLEIC, ADMIN?, XENOGEN?

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JAMES F. HALEY JR.
C/O FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	06 AUG 2009
Applicant's or agent's file reference ABX-PF/6 PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/00370	07 January 2005 (07.01.2005)	09 January 2004 (09.01.2004)

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

IPC: **A61K 48/00**(2006.01),**49/00**(2006.01);**C07K 16/30**(2006.01);**C12N 5/12**(2006.01)
USPC: 424/9.1,142.1;514/44;530/388.15,809;435/328

Applicant

AMGEN FREMONT, 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 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/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	05 August 2009 (05.08.2009)	Ron Schwadron, Ph.D. Telephone No. 571 272 1600

Form PCT/ISA/237 (cover sheet) (April 2007)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/00370

Box No. I 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 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. 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.

4. ☒ 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.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/00370

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. Claims 16-33,37-41,44-50 were not examined because they are improper multiple dependent claims.

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 16-33,37-41 and 44-50 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 16-33,37-41,44-50 were not examined because they are improper multiple dependent claims

☐ 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 Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/00370

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

1. Statement

Novelty (N)	Claims 4-6,8-15,42,43	YES
	Claims 1,2,35,36	NO
Inventive step (IS)	Claims 4-6,8-15,42,43	YES
	Claims 1-3,7,34-36,51-53	NO
Industrial applicability (IA)	Claims 1-15,34-36,42,43,51-53	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1,2,35,36 lack novelty under PCT Article 33(2) as being anticipated by US 2001/0046496 A1.

US 2001/0046496 A1 discloses human antibodies which bind MAdCAM (see [0051] and use of transgenic mice to produce such human antibodies (see [0023]). Said antibody would bind human cells because MAdCAM is found in humans and the antibody is administered to humans.

Claims 1-3,7,34-36,51-53 lack an inventive step under PCT Article 33(3) as being obvious over US 2001/0046496 A1 in view of US 2002/0065220 A1.

US 2001/0046496 A1 discloses human antibodies which bind MAdCAM (see [0051] and use of transgenic mice to produce such human antibodies (see [0023]). Said antibody would bind human cells because MAdCAM is found in humans and the antibody is administered to humans. US 2002/0065220 A1 discloses that antibody treatment using the administration of nucleic acids encoding a desired antibody was known in the art ([0305]). US 2001/0046496 A1 discloses human antibodies which bind MAdCAM and use of said antibodies in vivo in humans to treat disease (see [051]). The humanized antibodies that were produced would be screened for high affinity binding because high affinity binding antibodies would have greater effect in vivo. Obviously it would be desireable to determine if in vivo administered antibody was effective wherein the effectiveness could be determined by examining the effect of the antibody on the art known function of MAdCAM. FACs analysis is an art known method for detecting a desired cell population (aka MAdCAM positive leukocytes).

Claims 1-15,34-36,42,43,51-53 meet the criteria set out in PCT Article 33(4), and thus exude industrial applicability because the subject matter claimed can be made or used in industry.

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TELEFAX: (57) (1) 217-9211 (57) (1) 310-4995

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

Poderdante : PFIZER INC

Poder conferido el : 24/06/2003

Yo, EMILIO FERRERO, obrando como apoderado principal del poderdante arriba mencionado, mediante el presente escrito sustituyo el poder a mi otorgado a la doctora LUZ CLEMENCIA DE PAEZ, identificada con cédula de ciudadanía No. 35.456.344 y Tarjeta Profesional N°23.555, con todas las facultades que me fueron conferidas.

Hago la anterior sustitución conforme al artículo 66 del Código de Procedimiento Civil.

EMILIO FERRERO
T.P.A. N° 31.929
C.C. N° 438.019 de Usaquén

Acepto:

LUZ CLEMENCIA DE PAEZ
T.P.A. N° 23.555
C.C. No. 35.456.344 de Usaquén

COMO NOTARIA SEXTA DEL CIRCULO DE BOGOTA D.C. HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
BOGOTA D.C. REPUBLICA DE COLOMBIA
3 NOV 2003
NOTARIO ENCARGADO
Jaime Vargas Colombo
NOTARIO ENCARGADO
NOTARIA SEXTA DE BOGOTA

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NOTARIA SEXTA DE BOGOTA
RECONOCIMIENTO Y PRESENTACION PERSONAL
Bogotá, D.C.
Ante el 03 NOV 2009
NOTARIO SEXTO (E) DEL CIRCULO DE
BOGOTA D.C.
Compareció (eron) Emilio Fernández
Luz Clemencia de Páez

Quien(es) exhibió(aron) la(s) C.C.
CC # 438.019 (?) 31949
CC # 35456.344 (?) 23555
Y declaró(aron) que la(s) firma(s) que aparece(n) en el presente documento es(son) la(s) suya(s) y que el contenido del mismo es cierto.
En constancia se firma esta diligencia.

Emilio Fernández
Luz Clemencia Suárez

REPÚBLICA DE COLOMBIA
Jaime Vargas Colombo
NOTARIO ENCARGADO
NOTARIA SEXTA DE BOGOTA

LA NOTARIA SEXTA DEL CIRCULO DE BOGOTA D.C. HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
BOGOTA D.C. REPUBLICA DE COLOMBIA
3 NOV 2009
NOTARIO ENCARGADO

REPÚBLICA DE COLOMBIA
Jaime Vargas Colombo
NOTARIO ENCARGADO
NOTARIA SEXTA DE BOGOTA

606

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TELEFAX: (57) (1) 217-9211 (57) (1) 310-4995

Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

Poderdante : AMGEN FREMONT INC

Poder conferido el : 20/10/2006

Yo, EMILIO FERRERO, obrando como apoderado principal del poderdante arriba mencionado, mediante el presente escrito sustituyo el poder a mi otorgado a la doctora LUZ CLEMENCIA DE PAEZ, identificada con cédula de ciudadanía No. 35.456.344 y Tarjeta Profesional N°23.555, con todas las facultades que me fueron conferidas.

Hago la anterior sustitución conforme al artículo 66 del Código de Procedimiento Civil.

EMILIO FERRERO
T.P.A. N° 31.929
C.C. N° 438.019 de Usaquén

Acepto:

LUZ CLEMENCIA DE PAEZ
T.P.A. N° 23.555
C.C. No. 35.456.344 de Usaquén

COMO NOTARIA SEXTA DEL CIRCULO DE BOGOTA, D.C. HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
BOGOTA D.C. REPUBLICA DE COLOMBIA
3 NOV 2009
NOTARIO ENCARGADO
Jaime [illegible] Rambo
NOTARIO ENCARGADO
NOTARIA SEXTA DE BOGOTA
REPUBLICA DE COLOMBIA

44

NOTARIA SEXTA DE BOGOTA
RECONOCIMIENTO Y PRESENTACION PERSONAL 03 NOV 2009
Bogotá, D.C.
Ante el
NOTARIO SEXTO (E) DEL CIRCULO DE
BOGOTÁ D.C.
Compareció (eron) Emilio Ferreo
Luz Clemencia de Paez.

Quien(es) exhibió(aron) la(s) C.C.
CC# 438019 T #731929.
CC# 35.456.344 #923555
Y declaró(aron) que la(s) firma(s) que aparece(n)
en el presente documento es(son) la(s) suya(s) y
que el contenido del mismo es cierto.
En constancia se firma esta diligencia.

Emilio Ferreo
Luz Clemencia Goéliez

REPÚBLICA DE COLOMBIA
Jaime Vargas Ocambo
NOTARIO ENCARGADO
NOTARÍA SEXTA DE BOGOTÁ

COMO NOTARIA SEXTA DEL CIRCULO DE BOGOTÁ D.C. HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
BOGOTÁ D.C. - REPÚBLICA DE COLOMBIA
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REPÚBLICA DE COLOMBIA
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NOTARÍA SEXTA DE BOGOTÁ

Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-77165

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **583** DE

FECHA **18 DE DICIEMBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **14 DE MARZO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____ NO ____X____

607
608

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
Luz Clemencia de Páez

ASUNTO

Radicación	06 – 77165
Trámite	011
Evento	379
Actuación	430
Oficio	19429
Folios	003

Patente de Invención	☒	Patente de Modelo de Utilidad	☐		
Vía Nacional	☐				
Vía PCT (Fase Nacional)	☒	Cap.I	☒	Cap. II	☐

No. Solicitud Internacional PCT/US2005/000370
Fecha de Presentación Internacional 07/Enero/2005
Publicación internacional WO 2005/067620

Como resultado del Examen de Fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción:	Folios 267 a 381	04/08/2006
Reivindicaciones:	Folios 416 a 427	04/08/2006
	Folios 532 a 542	22/09/2006
Prioridad:	US 60/535,490	09/01/2004

2. Análisis de la Prioridad

Se acepta la reivindicación de Prioridad porque:
Esta solicitud fue presentada dentro del plazo establecido (Art. 9 D 486) y su contenido técnico corresponde con el de la prioridad reivindicada.

3. Objeto de la invención

Título de la solicitud: **"Anticuerpos contra MAdCAM"**

El objetivo de la invención es suministrar un anticuerpo que se une específicamente a la molécula de adhesión celular de adresina mucosal (MAdCAM) donde las CDRs del anticuerpo son humanas.

El problema planteado en esta solicitud es la necesidad de proveer moléculas que inhiban la unión de $\alpha_4\beta_7$ y el reclutamiento de leucocitos mediado por MAdCAM.

Para resolver este problema técnico la solicitud en estudio proporciona un anticuerpo que se une a MAdCAM humano, composiciones farmacéuticas que lo contienen y métodos para producir el mismo.

El objeto de la presente Solicitud se relaciona con la Clasificación Internacional de Patentes (CIP): A61K 48/00, 49/00; C07K 16/30, C12N 5/12.

4. Excepción a la Patentabilidad (Art 20 D 486 literal c y d)

El objeto de las reivindicaciones 14-16, 25, 29-31 no es patentable de acuerdo con el Art citado, por tratarse de métodos de tratamiento y métodos diagnósticos aplicados a humanos o animales.

Igualmente, las reivindicaciones 23 y 24 que se refieren a un animal o planta transgénico y al método para usarlo para producir el anticuerpo, no se consideran materia patentable de acuerdo con el literal c y d del artículo 20, de la D486.

5. Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

El kit reclamado en la reivindicación 26, esta conformado únicamente por el anticuerpo reclamado en las reivindicaciones precedentes por lo que en realidad lo que se reclama es el uso del mismo. Esta reivindicación no es patentable, de acuerdo con el Art 14.

6. De la solicitud de patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

El capítulo reivindicatorio carece de claridad y concisión por cuanto:

- El anticuerpo definido en las reivindicaciones 1-3 esta caracterizado a partir de parámetros, actividad, antígeno de unión, tipo de anticuerpo, lo cual no permite establecer la identidad del anticuerpo de la invención (definido a partir de su estructura) ni realizar una comparación frente al estado de la técnica. Estas características pueden colocarse como dependientes de la reivindicación principal que define la estructura completa del anticuerpo;

- La línea celular reclamada en la reivindicación 4 debe ser definida por el número de depósito y por la secuencia del anticuerpo completo, tal como esta en la reivindicación 9 aunque definiéndolos por los literales a) y b);

- Se debe reclamar el anticuerpo a partir de su estructura completa, esto es de las secuencias de las 6 CDRs que conforman las **cadenas pesada y cadena ligera** o de las secuencias de las regiones variables de **ambas cadenas,** indicando las posiciones en la cadena cuando sea el caso (reivindicaciones 5, 7-9,11). Esto aplica para todas las reivindicaciones que hacen referencia a fragmentos o porciones del anticuerpo o a productos obtenidos a partir de ellas (12, 13, 17);

- La reivindicación 6 define el anticuerpo a partir del resultado a alcanzar con el mismo. esta no es una característica técnica del mismo;

- El anticuerpo definido en la reivindicación 10 en sus diferentes conformaciones, debe ser caracterizado a partir de las secuencias que lo conforman, indicar las modificaciones realizadas para cada uno y estar plenamente sustentado en la descripción;

- Adicionalmente, debido al efecto que produce el cambio de un aminoácido de las regiones CDRs o regiones variables en la afinidad del anticuerpo, estas regiones deben ser definidas completamente y/o justificar cada una de las modificaciones realizadas. Por tanto, no se pueden definir a partir de porcentajes de identidad (reivindicación 12);

- La composición farmacéutica de la reivindicación 13 debe ser definida a partir de cada uno de sus componentes e indicar las proporciones de los mismos;

- El ácido nucleico reclamado en la reivindicación 18, debe ser definido a partir de la(s) secuencia(s) nucleótida(s) de la totalidad del anticuerpo, de manera que sea parte de la invención reclamada;

- El vector reclamado en la reivindicación 19 debe ser definido a partir de la(s) secuencia(s) heterólogas que contiene e indicar los elementos que lo conforman;

- El método reclamado en la reivindicación 24 no esta definido a partir de sus etapas fundamentales sino a partir del resultado a alcanzar con el uso del anticuerpo de la invención;

- La vacuna de la reivindicaciones 27 y 28 esta definida a partir de los mismos componentes de la composición farmacéutica. Adicionalmente, a partir de la descripción no es aparente el sustento de la misma;

7. Determinación del Estado de la Técnica

El estado de la técnica se determinó con base en la

Fecha de presentación de la solicitud de prioridad: 09 de enero de 2004 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación
D1	US 6,551,593	"Treatment of inflammatory bowel disease by inhibiting binding and/or signaling through $\alpha_4\beta_7$ and its ligands and madcam"	22/04/2003

Resumen del documento citado:

D1: La invención se relaciona con el tratamiento de individuos con enfermedad asociada con incremento de leucocitos en el tracto gastrointestinal o otros tejidos, como resultado de la unión de leucocitos en el endotelio intestinal que expresa la molécula MAdCAM (tal como la enfermedad inflamatoria de intestino), comprendiendo administrar un anticuerpo el cual inhibe la unión de leucocitos al endotelio MAdCAM (resumen D1)
http://www.google.com/patents Ingresando el número 6551593.

8. Examen de Patentabilidad (Art 14 D486)

Novedad (Art16 D486)

La reivindicación 1 consiste en un anticuerpo monoclonal humano o una porción de unión de antígeno de éste que se une específicamente a la molécula de adhesión de célula de adresina de mucosa humana (MAdCAM).

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Caracteristicas esenciales (Rv 1)	D1
Anticuerpo monoclonal humano o porción de unión de antigeno de este	Anticuerpo monoclonal o porción de unión de antigeno de este (Reivindicación 1)
se une especificamente MAdCAM	Epitope especifico MAdCAM (resumen, lineas 50-65).

El documento D1 divulga un anticuerpo monoclonal o porción de unión al antigeno, que se une a MAdCAM y/o integrina $\alpha_4\beta_7$ (ver columna 2 lineas 35-45). Este documento menciona además diferentes anticuerpos que se unen a estas mismas moléculas y menciona las técnicas conocidas que se pueden utilizar para modificarlos (ver columna 2, lineas 46-66). Adicionalmente, el documento indica las especies en las cuales puede ser aplicable el anticuerpo mencionando ratón, rata, conejo, oveja, entre otros (columna 3 linea 1-3) y las patologías que pueden ser tratadas (ver reivindicaciones).

En el ejemplo 1, se ilustra el uso del anticuerpo para inhibir la infiltración de leucocitos, al aplicar los anticuerpos anti- MAdCAM, denominados FIB21 y FIB30 que han sido previamente caracterizados y divulgados (ver columnas 5-6).

Este documento también indica las formas alternativas que se pueden usar para el anticuerpo, mencionando fragmentos Fv, Fab, Fab´y $F(ab')_2$ (ver columna 3 linea 40-48) y las modificaciones a realizar, tales como anticuerpo humanizado, quimérico (ver reivindicaciones).

De esta manera, el anticuerpo de la solicitud definido en las reivindicaciones 1-6 habia sido anticipado por D1, haciendo que incumpla el artículo 16 de la D486.

9. Conclusión

Los requisitos de patentabilidad de la presente solicitud están afectados asi:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 6,551,593	1 y dependientes	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.

JOSÉ LUIS SALAZAR LÓPEZ
Director de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha 15 DIC. 2011.

Elaboró: N.Lamprea NLB.
Revisó: Consuelo Leguizamón L.

Expediente 06-77165 1er Art 45