

388

Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-128814-00002-0000

Fecha: 2008-02-20 16:40:35 Dep. 2020 NUECREACIONE
Tra. 11 PATENTE/II Eve: 378 FASENACIONALI
Act: 329 CTOINFORMACION Folios: 11

E. S. D.

Referencia: Expediente No. 07.128.814

Solicitud de Patente de Invención titulada: "anticuerpos monoclonales anti-trkb y usos de los mismos"

Solicitante: Wyeth

MEMORIAL DE ALCANCE

ÁLVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogotá D.C., identificado según aparece al pie de mi firma, en mi condición de apoderado de la sociedad en referencia, manifiesto lo siguiente:

El día 5 de diciembre de 2007, bajo el número de radicación 07.128.814, presenté la solicitud de patente de invención de la referencia, para la cual adjunto Reporte Preliminar Internacional sobre Patentabilidad Capítulo I.

Atentamente,

ÁLVARO CORREA ORDÓÑEZ

C.C.No.79.143.366 de Usaquén

T.P.20.281

Anexo: Reporte Preliminar Internacional sobre Patentabilidad Capítulo I.

BOGLMS/BOGDMS-103987-V1-.DOC - P2007/000373

394

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 2004658-0338	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2006/021878	International filing date (day/month/year) 05 June 2006 (05.06.2006)	Priority date (day/month/year) 06 June 2005 (06.06.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant WYETH		

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).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

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.

3. This report contains indications relating to the following items:

- | | |
|--|---|
| ☒ 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 |

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).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 06 December 2007 (06.12.2007)
Facsimile No. +41 22 338 82 70	Authorized officer Agnes Wittmann-Regis
Form PCT/IB/373 (January 2004)	e-mail: pt06.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43b/s.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2006/021878

International filing date (day/month/year)
05.06.2006

Priority date (day/month/year)
06.06.2005

International Patent Classification (IPC) or both national classification and IPC
INV. C07K16/28 A61K39/395 G01N33/577 C12N5/18 A61P3/00 A61P17/00 A61P25/00 A61P31/00 A61P35/00

Applicant
WYETH

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 43b/s.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 usually 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:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523655 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Bayer, Annette

Telephone No. +49 89 2399-7103



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/021878

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. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, 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:
3. ☒ 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.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43b/s.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43b/s.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/021878

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. 61-68 (regarding IA)

because:

- ☒ the said international application, or the said claims Nos. 61-68 (regarding IA) relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

- ☐ 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 the whole application or 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/US2006/021878

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)	Yes: Claims	2-9,21-24,26-29,34-45,47-57
	No: Claims	1,10-20,25,30-33,46,58-70
Inventive step (IS)	Yes: Claims	
	No: Claims	1-70
Industrial applicability (IA)	Yes: Claims	1-60,69,70
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

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

see separate sheet

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:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/021878

Re Item III

Claims 61.68 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

1. For the assessment of the present claims 61-68 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.
2. Reference is made to the following documents:
 - D1: R&D SYSTEMS, INC.: "Monoclonal Anti-mouse TrkB Antibody, Catalog Number: MAB1494" 21 December 2004 (2004-12-21), R&D SYSTEMS, INC. , XP002411650
 - D2: R&D SYSTEMS, INC.: "Monoclonal Anti-human TrkB Antibody, Catalog Number: MAB3971" 13 September 2004 (2004-09-13), R&D SYSTEMS, INC. , XP002411651
 - D3: R&D SYSTEMS, INC.: "Monoclonal Anti-human TrkB Antibody, Catalog Number: MAB397" 7 September 2003 (2003-09-07), R&D SYSTEMS, INC. , XP002411652
 - D4: GEETHA T ET AL: "Association of the atypical protein kinase C-interacting protein p62/ZIP with nerve growth factor receptor TrkA regulates receptor trafficking and Erk5 signaling" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BIRMINGHAM,, US, vol. 278, no. 7, 5 December 2002 (2002-12-05), pages 4730-4739, XP002372986 ISSN: 0021-9258
 - D5: WO 95/15180 A (UNIV CALIFORNIA [US]) 8 June 1995 (1995-06-08)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/021878

D6: WO 96/01837 A (PHILADELPHIA CHILDREN HOSPITAL [US]) 25 January 1996 (1996-01-25)

D7: QIAN MING D ET AL: "Novel agonist monoclonal antibodies activate TrkB receptors and demonstrate potent neurotrophic activities" JOURNAL OF NEUROSCIENCE, vol. 26, no. 37, September 2006 (2006-09), pages 9394-9403, XP009078184 ISSN: 0270-6474

As long as not otherwise indicated, reference is made to the passages cited in the international search report.

3. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 10-20, 25, 30-33, 46, 58-70 is not new in the sense of Article 33(2) PCT.

- 3.1 Present claims 58 and 60 relate to products, i.e. a hybridoma or a monoclonal antibody, respectively, wherein they are characterized by a process. However, a product is not rendered novel merely by the fact that it is produced by means of a new process. Accordingly, any hybridoma producing an anti-TrkB monoclonal antibody as well as any anti-TrkB monoclonal antibody known in the art deprives said claims from novelty.
- 3.2 D1 discloses a monoclonal anti-mouse TrkB antibody (IgG2b-isotype) directed against the extracellular domain which shows 75-100% cross-reactivity with human TrkB and no cross-reactivity with human TrkA, rat TrkA or mouse TrkC. D1 further teaches the use of said antibody in Western Blots, ELISA and for immunohistochemistry.
Thus, D1 anticipates the novelty of present claims 1, 10, 32, 33, 46, 58-60 and 69.
- 3.3 D2 discloses a monoclonal anti-human TrkB antibody (IgG1 isotype) directed against the extracellular domain which shows no cross-reactivity with human TrkA, rat TrkA, mouse TrkB, human TrkC or mouse TrkC. D2 further teaches the use of said antibody in Western Blots, ELISA and flow cytometry. Accordingly, in view of D2, the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/021878

subject-matter of present claims 1, 10-20, 30, 46, 58-60 and 69 is not novel.

- 3.4 D3 discloses a monoclonal anti-human TrkB antibody (IgG2b isotype) directed against the extracellular domain which shows no cross-reactivity with human TrkA, rat TrkA and human TrkC. D3 further teaches the use of said antibody in Western Blots, ELISA and immunohistochemistry. Accordingly, in view of D2, the subject-matter of present claims 1, 10-20, 32, 46, 58-60 and 69 is not novel.
- 3.5 D4 uses a mouse monoclonal IgG2a antibody binding to TrkA, TrkB and TrkC of human, mouse and rat origin which finds use in western blots, immunoprecipitation and immunofluorescence according to manufactures data sheet (SANTA CRUZ BIOTECHNOLOGY, INC.: "Trk (b-3): sc-7268"). Thus, D4 anticipates the novelty of present claims 1, 31, 33, 46, 58-60 and 69.
- 3.6 D5 teaches the generation and use in therapy and diagnosis of agonistic antibodies against TrkA, TrkB or TrkC including monoclonal antibodies. Accordingly, D5 anticipates the novelty of present claims 1, 46 and 58-69.
- 3.7 D6 relates to full-length TrkB and its uses. D6 further teaches the generation of monoclonal antibodies directed against the intracellular domain of human TrkB and use thereof for diagnosis, treatment and TrkB purification. Thus, D6 anticipates the novelty of present claims 1, 10, 15, 25, 46, 58-60, 69 and 70.

4. Inventive step

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2-9, 21-24, 26-29, 34-45 and 47-57 does not involve an inventive step in the sense of Article 33(3) PCT.

- 4.1 Claims 2-9, 21-24, 26-29 and 34-41 refer to features of human anti-TrkB antibodies which appear to be arbitrarily selected and as they simply amount to setting the teachings of any of D1-D6 into practice do not involve an inventive step. In particular the epitopes suggested by claims 38-41 are considered to be arbitrarily selected which, as they do not appear to result in any unforeseeable technical effect, do not

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2006/021878

establish an inventive step.

- 4.2 Claims 42, 43 and 47-57 refer to subject-matter obtainable by routine experimentation or involving the said, once the teaching of any of D1-D6 is set into practice. The corresponding technical features do not produce any unforeseeable technical effect, but appear to be arbitrarily selected. Hence, these claims are not considered as inventive.

Re Item VII

1. With regard to the wording "one", present claim 38 seems to be redundant in view of claim 38.
2. Present claims 41, 44 and 45 seem to be redundant in view of claims 40, 38 or 45, respectively.
3. A document reflecting the prior art described on page 1 line 8-page 2 line 25 is not identified in the description (Rule 5.1(a)(ii) PCT).
4. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D6 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

1. Claims 1-29, 33-41, 44 and 45 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.
2. The present application addresses the problem of providing potent and selective agonists of TrkB (see page 2 lines 19-25). Thus, the agonistic activity is considered as an essential feature to the definition of the invention.