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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Señores

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

E. S. D.

REF: Expediente No. 07 080736- Solicitud de Patente FASE NACIONAL
Corresp. a la Solicitud Internacional PCT/US2006/004926
a favor de **GENENTECH, INC.**

Titulada: INHIBICIÓN DE LA LIBERACIÓN DE HER2 ("HER2 SHEDDING")
CON ANTAGONISTAS DE METALOPROTEASAS DE MATRIZ

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492, obrando como apoderado de la sociedad **GENENTECH, INC**, según lo acredita el documento de Poder presentado en esa División, me permito anexar al presente escrito el siguiente documento:

1. Reporte Preliminar Internacional sobre la Patentabilidad (Formas PCT/IB/373 y PCT/ISA/237).

De la señora jefe atentamente,


JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
Cra. 7 No. 71-21, Torre B, Piso 4

Bogotá, 26 de diciembre de 2007
MEVaac

04W4/ac

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

De-docketed

To:

KUBINEC, Jeffrey, S.
GENENTECH, INC.
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MS 49
South San Francisco, CA 94080
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
23 August 2007 (23.08.2007)

Applicant's or agent's file reference
P2195R1

IMPORTANT NOTICE

International application No.
PCT/US2006/004926

International filing date (day/month/year)
09 February 2006 (09.02.2006)

Priority date (day/month/year)
09 February 2005 (09.02.2005)

Applicant

GENENTECH, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

RECEIVED

AUG 30 2007

GENENTECH, INC.
LEGAL DEPT.

The International Bureau of WIPO
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1211 Geneva 20, Switzerland

Authorized officer

Yolaine Cussac

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PCT

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

(PCT Rule 44bis)

Applicant's or agent's file reference P2195R1	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2006/004926	International filing date (day/month/year) 09 February 2006 (09.02.2006)	Priority date (day/month/year) 09 February 2005 (09.02.2005)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant GENENTECH, INC.			

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 6 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 14 August 2007 (14.08.2007)
Facsimile No. +41 22 338 82 70		Authorized officer Yolaine Cussac
		e-mail: pt11.pct@wipo.int

Form PCT/IB/373 (January 2004)

PCT 4

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.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/US2006/004926

International filing date (day/month/year)
09.02.2006

Priority date (day/month/year)
09.02.2005

International Patent Classification (IPC) or both national classification and IPC
INV. C12N15/11 C12N9/64 A61K39/395 G01N33/574 A61P35/00

Applicant
GENENTECH, 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 43bis.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 66.1b/s(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:



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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Brück, Marianne

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/004926

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:

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)	Yes: Claims	1-12,17-19,
	No: Claims	13-16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-21
Industrial applicability (IA)	Yes: Claims	cf. SepSheet point V 5.
	No: Claims	

2. Citations and explanations

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

Section II

Priority

The present assessment of novelty and inventive step has been made on the assumption that the claims are entitled to their earliest declared priority date. D11, the cited P-document, discloses the claimed subject-matter and might, therefore, also be considered for the question of novelty or become state of the art in case of an invalid priority.

Section V

1. Subject matter

The independent claims relate to methods

- for inhibiting HER2 shedding with a matrix metalloprotease (MMP) antagonist (claim 1);
- for reducing HER2 extracellular domain (ECD) serum level in a mammal with a matrix metalloprotease (MMP) antagonist (claim 11);
- for treating cancer with a matrix metalloprotease (MMP) antagonist (claim 13);
- for treating a HER inhibitor resistant cancer with a matrix metalloprotease (MMP) antagonist (claim 17);
- for reducing p95 HER2 level in a cell with a matrix metalloprotease (MMP) antagonist (claim 19);
- of diagnosis by evaluating MMP-15 (MT2-MMP) as indication for an elevated p95 HER2 or shed HER2 serum level leading to a poor clinical prognosis (claim 20).

2. Prior art

The documents are numbered chronologically as they appear in the Search Report.

3. Novelty

Claims 13-16 and 20-21 are not novel because the treatment of cancer with matrix metalloprotease inhibitors has already been disclosed in the cited prior art (for details concerning the claims and relevant passages in the affected documents please cf. to the International Search Report).

4. Inventive Step

Claims 13-16 and 20-21 are not novel, therefore, also not inventive.

The remaining claims have been implicitly disclosed/ are obvious in the light of the numerous cited documents which have already disclosed the correlation of HER2 shedding - matrix metalloprotease - cancer (for details concerning the claims and relevant passages in the affected documents please cf. to the International Search Report).

5. Industrial applicability

For the assessment of the present claims 1-21 on the question whether it is industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims.

The EPO does not, for example, recognize as industrially applicable the subject matter of claims to the use of a compound in medical treatment, but may allow 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. In case some methods are meant to be conducted only *in vitro*, "*in vitro*" should be introduced in the affected claims.

Section VIII

The application does not fulfill the requirements of Article 6, because dependant claim 18 is unclear due to the following:

- claim 18 is dependant from claim 17 relating to the treatment of HER inhibitor resistant cancer with a matrix metalloprotease (MMP) antagonist, but is specifying the HER inhibitor trastuzumab. This is inconsistent and contradictory and, renders, therefore, the claim unclear.