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Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. _____ S. _____ D. _____

Referencia: Expediente No. 07.080.213

Solicitud de Patente de Invención titulada: "Formulaciones de CCI-779
oralmente biodisponibles."

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 6 de agosto de 2007, bajo el número de radicación 07.080.213, presenté la solicitud de patente de invención de la referencia, para la cual adjunto informe preliminar internacional sobre patentabilidad, capítulo I del tratado de cooperación en materia de patentes.

Atentamente,

ÁLVARO CORREA ORDÓÑEZ

C.C No. 79.143.366 de Usaquén

T.P. 20.281

Anexo: Informe preliminar internacional sobre patentabilidad, capítulo I

PATENT COOPERATION TREATY

PCT/US2006/006991

From the INTERNATIONAL BUREAU

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PCT

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

To:

KODROFF, Cathy, A.
HOWSON AND HOWSON
321 Norristown Road, Suite 200
Spring House Corporate Center, P.O. Box 457
Spring House, Pennsylvania 19477
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 30 August 2007 (30.08.2007)		
Applicant's or agent's file reference AM-101822PCT		IMPORTANT NOTICE
International application No. PCT/US2006/006991	International filing date (day/month/year) 13 February 2006 (13.02.2006)	
		Priority date (day/month/year) 15 February 2005 (15.02.2005)
Applicant WYETH et al		

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

RECEIVED
SEP 6 2007
By _____

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No. +41 22 338 82 70	e-mail: pt04.pct@wipo.int

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 AM-101822PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2006/006991	International filing date (day/month/year) 13 February 2006 (13.02.2006)	Priority date (day/month/year) 15 February 2005 (15.02.2005)
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 7 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 Facsimile No. +41 22 338 82 70	Date of issuance of this report 21 August 2007 (21.08.2007)
	Authorized officer Athina Nickitas-Etienne e-mail: pt04.pct@wipo.int

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

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/US2006/006991	International filing date (day/month/year) 13.02.2006	Priority date (day/month/year) 15.02.2005
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International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/20 A61K9/48 A61K31/4745

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 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 66.1bis(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: 523656 epmu d Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Sindel, U Telephone No. +49 89 2399-7064
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/006991

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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/006991

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. 6, 8, 11, 13-19

because:

- ☒ the said international application, or the said claims Nos. 14-18 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. 6, 8, 11, 13, 16, 18 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ 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 13ter.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

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/006991

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	1-5, 7, 9-10, 12, 14-15, 17, 19
	No: Claims	
Inventive step (IS)	Yes: Claims	1-5, 7, 9-10, 12, 14-15, 17, 19
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-13, 19
	No: Claims	

2. Citations and explanations

see separate sheet

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

International application No.

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Item III

Claims 14-18 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).

The subject-matter of present claims 6, 8, 11, 13, 16 and 18 is not clear. According to these dependent claims, the content of active agent CCI-779 in the oral dosage form is either 5 to 35 mg or 30 mg. In contrary, the correspondent independent claims 1 and 3 define the composition of the oral dosage form via the bioavailability of a composition containing **25 mg** CCI-779. Hence, the subject-matter of dependent claims 6, 8, 11, 13, 16 and 18 is broader and it is not clear for the person skilled in the art how these dosage forms should be realized with regard to the claimed bioavailability.

Item V

- 1 Reference is made to the following documents:

D1: US 2002/091137

D2: US 5 362 718

The Applicant is informed that there exists an intermediate document which might become relevant in the European Phase of the application. The intermediate document is WO 2005/070393 having a priority of 08.01.2004, a date of filing of 14.12.2004 and a publication date of 4.08.2005.

- 2 Novelty and Inventive Step

The subject matter of claims 1-5, 7, 9-10, 12, 14-15, 17 and 19 seems to be new in the sense of Article 33(2) PCT and to involve an inventive step in the sense of Article 33(3) PCT.

The problem to be solved in the present application is the provision an oral solid formulation of the rapamycin ester CCI-779 showing high bioavailability of the active compound.

The solution provided is a direct-compressible pharmaceutical composition

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

International application No.

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comprising CCI-779 in micronized form having a bioavailability as defined in claim 1.

Closest prior art is document D1 disclosing a liquid formulation of CCI-779 for parenteral administration (see paragraphs [0014], [0020]). Other possible galenical formulations like e.g. powders and tablets are mentioned without showing examples (see paragraphs [0038]-[0044]). There is no hint given that an improved bioavailability of CCI-779 could be reached by using the active in micronized form and formulating a direct-compressed tablet.

4 Industrial applicability

For the assessment of the present claims 14-18 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.

The subject-matter of claims 1-5, 7, 9-10, 12 and 19 is industrially applicable.