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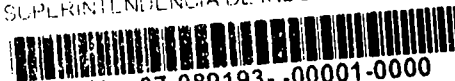
Señor

Superintendente Delegado para la Propiedad Industrial

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. _____ S. _____ D. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-089193- -00001-0000

Fecha 2007-12-10 16:32:31 Dep. 2020 NUECREACION
Tra 11 PATENTILYII Lva. 378 FASENACIONALI
Act 320 CIOINFORMACION Folios: 8

Referencia: Expediente No. 07.089.193

Solicitud de Patente de Invención titulada: "Recuperación de CCI-779 a partir de licores madre"

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 30 de agosto de 2007, bajo el número de radicación 07.089.193, 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

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
Howson and Howson
501 Office Center Drive
Suite 210
Fort Washington, Pennsylvania 19034
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
20 September 2007 (20.09.2007)

Applicant's or agent's file reference
AM-100921PCT

IMPORTANT NOTICE

International application No.
PCT/US2006/006207

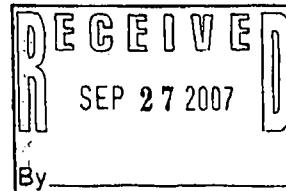
International filing date (day/month/year)
22 February 2006 (22.02.2006)

Priority date (day/month/year)
02 March 2005 (02.03.2005)

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)



The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Beate Giffo-Schmitt

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PATENT COOPERATION TREATY

PCT

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

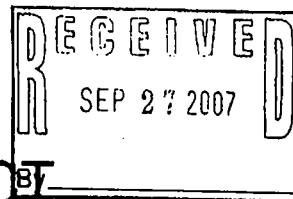
(PCT Rule 44bis)

Applicant's or agent's file reference AM-100921PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2006/006207	International filing date (day/month/year) 22 February 2006 (22.02.2006)	Priority date (day/month/year) 02 March 2005 (02.03.2005)	
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 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 Facsimile No. +41 22 338 82 70 Form PCT/IB/373 (January 2004)	Date of issuance of this report 11 September 2007 (11.09.2007)
	Authorized officer Beate Giffo-Schmitt e-mail: pt03.pci@wipo.int

PATENT COOPERATION TREATY



From the
INTERNATIONAL SEARCHING AUTHORITY

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/US2006/006207

International filing date (day/month/year)
22.02.2006

Priority date (day/month/year)
02.03.2005

International Patent Classification (IPC) or both national classification and IPC
INV. C07D498/18

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

Helps, I

Telephone No. +49 89 2399-8209



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/006207

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 43bis.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 43bis.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/US2006/006207

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

1. Statement

Novelty (N)	Yes: Claims	1-15
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-15
Industrial applicability (IA)	Yes: Claims	1-15
	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

V. CITATIONS AND EXPLANATIONS

The following documents are mentioned in this Written Opinion.

US-A1-2005 033046	(A)
WO-A-2005 010010	(B)
US-B1-6,277,983	(C)
US-A-5,362,718	(D)

The novel feature of the process of claim 1 is the addition of a buffer solution of pH 5 to 5.5 to a concentrated mother liquor obtained from the preparation of CCI-779. Claims 2 to 15 which describe preferred embodiments of the process of claim 1 are novel by consequence. Claims 1 to 15 therefore meet the Novelty requirements of Article 33(2) PCT.

The closest prior art, document (A), describes the preparation of CCI-779 via a boronate ester. The B to C isomer ratio of the boronate ester is increased using a sodium acetate buffer (see page 4, paragraphs 56-57). After reaction with 2-methyl-2,4-pentanediol, the reaction mixture is worked up by concentrating to a foam, adding diethyl ether and heptane, and redissolving the precipitated solid in acetone. After filtering, the solution is again concentrated to a foam, ether and heptane added and the solid dried to give CCI-779 (see page 8, paragraph 72). Starting from this document, the problem underlying the present application is to be seen in the provision of improved recovery of CCI-779 from the reaction mixture.

It is known from document (A) that the B to C isomer ratio of the 42-ester boronate of rapamycin can be increased using a buffer in the range pH 5 to 6, e.g. sodium acetate. Thus the yield of the B-isomer of the 42-boronate ester was increased by modification of the pH of the mother liquor (see paragraph 56). Document (B) also teaches that the B to C isomer ratio of CCI-779 can be controlled using buffer solutions (see pages 3 to 4). In this case, the C isomer was desired, and obtained by controlling the equilibrium with a pH 8 to 9. However, it is also stated that isomer B is actually favoured in the equilibrium.

It is taught in document (A) that the B isomer of the 42-boronate ester of rapamycin is less

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

International application No.

PCT/US2006/006207

soluble than the C-isomer (see paragraph 56), and that the B to C isomer ratio is increased using the sodium acetate buffer. The skilled man would have used this information to deduce the key step in the presently claimed process of adding a buffer to the mother liquor of CCI-779 in order to increase the B to C isomer ratio thereof, and hence to enable additional CCI-779 to be recovered from the mother liquor.

Consequently, inventive step (Article 33(3) PCT) cannot be recognised because the problem of obtaining improved recovery of CCI-779 appears to have been solved in an obvious manner. The Applicant is therefore requested to submit further information and argumentation in order to make credible the involvement of inventive step for the presently claimed process.

VII. CERTAIN DEFECTS IN THE INTERNATIONAL APPLICATION.

In order to meet the requirements of Rule 5.1(a)(ii) PCT, document (B) should be identified in the description and the relevant prior art disclosed therein should be briefly discussed.

VIII. CERTAIN OBSERVATIONS ON THE INTERNATIONAL APPLICATION

The use of the term "about" in the pH range defined in claim 1 renders the claimed range unclear (Article 6 PCT).