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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Referencia: Expediente No. 08.002.354

Solicitud de Patente de Invención titulada: "Formas de dosificación de liberación retardada orales altamente biodisponibles de succinato de o-desmetilvenlafaxina"

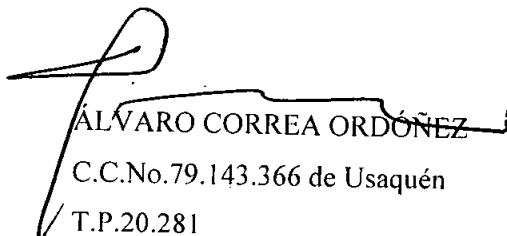
Solicitante: Wyeth.

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 11 de enero de 2008, bajo el número de radicación 08.002.354 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/US2006/027106

From the INTERNATIONAL BUREAU

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

Date of mailing (day/month/year)
24 January 2008 (24.01.2008)

Applicant's or agent's file reference
AM-101721PCT

IMPORTANT NOTICE

International application No.
PCT/US2006/027106

International filing date (day/month/year)
13 July 2006 (13.07.2006)

Priority date (day/month/year)
15 July 2005 (15.07.2005)

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)

JAN 31 2008

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

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PATENT COOPERATION TREATY

PCT

JAN 31 2008

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

(PCT Rule 44bis)

Applicant's or agent's file reference AM-101721PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2006/027106	International filing date (day/month/year) 13 July 2006 (13.07.2006)	Priority date (day/month/year) 15 July 2005 (15.07.2005)	
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 9 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).

	Date of issuance of this report 16 January 2008 (16.01.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Beate Giffo-Schmitt e-mail: pt03.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 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 belowInternational application No.
PCT/US2006/027106International filing date (day/month/year)
13.07.2006Priority date (day/month/year)
15.07.2005International Patent Classification (IPC) or both national classification and IPC
INV. A61K9/32 A61K9/50 A61K31/135Applicant
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
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Luangkhot, Nathalie

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2006/027106

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/US2006/027106

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. 23-25 with respect to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 23-25 with respect to industrial applicability 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 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

82

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2006/027106

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	
	No: Claims	<u>1-26</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-26</u>
Industrial applicability (IA)	Yes: Claims	<u>1-22,26</u>
	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

Re Item I.

- 1) The documents cited in the International Search Report (ISR) were numbered respectively from D1-D7; this numbering results from the citation order in the ISR and will be used for the procedure. Unless otherwise specified, the cited passages of each document in the ISR will be considered.

- D1: WO 2005/077340 A (WYETH CORP [US]; DIORIO CHRISTOPHER RICHARD [US]; SHAH SYED M [US]; FA) 25 August 2005 (2005-08-25)
D2: WO 2004/096186 A (DEXCEL LTD [IL]; VOLPERT SIMA [IL]; AVRAMOFF AVI [IL]) 11 November 2004 (2004-11-11)
D3: US-B1-6 274 171 (SHERMAN DEBORAH M [US] ET AL) 14 August 2001 (2001-08-14)
D4: US 2003/190352 A1 (ESCOI JUAN CUCALA [ES] ET AL) 9 October 2003 (2003-10-09)
D5: US-B1-6 703 044 (PINHASI ADEL [IL] ET AL) 9 March 2004 (2004-03-09)
D6: WO 00/76955 A (AMERICAN HOME PROD [US]) 21 December 2000 (2000-12-21)
D7: US 2006/003007 A1 (ODIDI ISA [CA] ET AL) 5 January 2006 (2006-01-05)

For the present examination it would be assumed that the priority date of present application is valid so that the P-document D1 and D7 which fall under the definition of Rule 70.10 PCT is not considered for the PCT phase. However the applicant's attention is drawn with the fact that the intermediate Documents D1 and D7 may be relevant for the European Regional Phase with regard to novelty **and** eventually to inventive step.

- 2) Result-to be achieved

The formulations in claims 1-2 such as "[...] having a delayed release of at least about one hour and a sustained release over multiple hours to provide a total release of greater than about 85% within 12 to 14 hours" do not delimit the scope of the protection to be sought and are rather to be construed as an attempt to define the invention by a **result to be achieved**, in particular when they only amount to claiming the underlying technical problem.

Such definitions are only allowable under the conditions elaborated in the Guidelines C-III, 4.7. In this instance, however, **such formulations are not allowable because it appears possible to define the subject-matter in more concrete terms, viz. in**

terms of how the effect is to be achieved by incorporating for example the type and amount of excipients used, ...

Hence applicant's attention is drawn with the fact such formulations in claims 1-2 **are not recognized as a technical feature** that can confer novelty to the application, **but as a result to be achieved and therefore will be ignored while assessing novelty.**

Re Item III.

- 3) Claims 23-25 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.

- 4) Novelty and inventive step
- 4a) The subject-matter of independent claim 1 is not novel and/or not inventive in the light of D1-D7 because these latter describe a superbioavailable venlafaxine sustained release composition comprising a/ a core containing at least venlafaxine, a water insoluble filler such as microcrystalline cellulose, b/ a controlled release coat comprising ethylcellulose.
- 4b) Dependent claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.
- 4c) Should the applicant renders the subject-matter of the present application novel by pointing out the importance a technical feature that is not described explicitly in prior art or by introducing into the claims the use of a **specific ingredient or a specific amount** or whatever, inventive step may be recognized **only if he demonstrates** that **a surprising and/or synergetic effect** (with support of experimental data comparing

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)

International application No.

PCT/US2006/027106

the properties of present and prior art compositions) is attributed to the distinguishing technical feature that the skilled man in the art will not be able to deduct from the prior art.

In the absence of a **surprising effect** directly attributed to the distinguishing feature or **evidence of a particular prejudice**, inventive step cannot be acknowledged because the introduced/distinguishing technical feature will be considered as an **obvious alternative** that the skilled man in the art will perform **routinely** in order to obtain a formal novelty.

It is indeed a **matter of routine** for the skilled man in the art to prepare a superbioavailable sustained release composition of any drugs, in order to enhance stability, bioavailability and obtain less side effects, by using conventional ingredients such the one used in D1-D7. **The applicant should provide evidences that it was not obvious** to select a specific mixture used at a specific amount.

The closest prior art document(s) should be identified, and the problem-solution approach should be applied.

Re Item VII.

- 5) Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application.
- 6) For the assessment of the present claims 23-25 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.

91

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)

International application No.

PCT/US2006/027106

- 7) Contrary to the requirements of Rule 5.1(a)(ii) PCT, it seems that the relevant background art disclosed in the documents D1-D7 is not mentioned in the description, nor are these documents identified therein.
- 8) The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). Preferably these indications should be submitted in handwritten form on a copy of the relevant parts of the application as filed.

- 9) During the written procedure the applicant is kindly requested to take account of the above objections and give convincing argumentations. It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. Should the applicant nevertheless regard some particular matter as patentable, an independent claim should be filed taking account of Rule 6.3(b) (i), (ii) PCT (two part form claim). The applicant should also indicate in the letter of reply the difference of the subject-matter of the new claim vis-à-vis the state of the art and the significance thereof.