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Señora

Alix Carmenza Cespedes de Vergel

Jefe de Division de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E S D

Referencia Expediente No 06 128 285

Solicitud de Patente de Invencion titulada "Regimenes y kits contracepticos antagonistas del receptor de progesterona"

Solicitante Wyeth

MEMORIAL DE ALCANCE

ALVARO CORREA ORDÓÑEZ, mayor de edad y vecino de Bogota D C , identificado según aparece al pie de mi firma, en mi condicion de apoderado de la sociedad en referencia manifiesto lo siguiente

El dia 21 de diciembre de 2006, bajo el numero de radicacion 06 128 285, presente la solicitud de patente de invencion de la referencia, para la cual adjunto informe preliminar internacional sobre patentabilidad, capitulo I del tratado de cooperacion en materia de patentes

Atentamente,

ALVARO CORREA ORDÓÑEZ

C C No 79 143 366 de Usaquen

T P 20 281

Anexo Informe preliminar internacional sobre patentabilidad, capitulo I

BOG: ML/BOGDMS 79674 V1 DOC

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

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ETATS UNIS D AMERIQUE

Date of mailing (day/month/year)
18 January 2007 (18 01 2007)

Applicants or agents file reference
AM 101674PCT

IMPORTANT NOTICE

International application No
PCT/US2005/023798

International filing date (day/month/year)
06 July 2005 (06 07 2005)

Priority date (day/month/year)
07 July 2004 (07 07 2004)

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

Philippe Becamel

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Form PCT/IB/326 (January 2004)

PCT

nr 207 215

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

(PCT Rule 44bis)

Applicant's or agent's file reference AM 101674PCT	FOR FURTHER ACTION See item 4 below	
International application No PCT/US2005/023798	International filing date (day/month/year) 06 July 2005 (06 07 2005)	Priority date (day/month/year) 07 July 2004 (07 07 2004)
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 8 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 <table border="0"> <tr> <td>☒ Box No I</td> <td>Issues of the report</td> </tr> <tr> <td>☐ Box No II</td> <td>Priority</td> </tr> <tr> <td>☒ Box No III</td> <td>Non establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐ Box No IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td>☒ Box No V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td> </tr> <tr> <td>☐ Box No VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☐ Box No VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☐ Box No VIII</td> <td>Certain observations on the international application</td> </tr> </table> 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)	☒ Box No I	Issues 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
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☐ Box No VIII	Certain observations on the international application															

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 09 January 2007 (09 01 2007) Authorized officer Philippe Becamel e-mail: p12@wipo.int
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PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

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To see form PCT/ISA/220 02/02 PT12
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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/US2005/023798	International filing date (day/month/year) 06 07 2005
Priority date (day/month/year) 07 07 2004	
International Patent Classification (IPC) or both national classification and IPC A61K31/404, A61K31/536, A61K31/537, A61P15/18	
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"). However, 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 three 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 80288 Munich Tel +49 89 23699 - 0 Tx 523696 epmu d Fax +49 89 23699 4465	Authorized Officer Buttner, U Telephone No +49 89 23699 7841 
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No	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 unless otherwise indicated under this item ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 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 ☐ in written format ☐ in computer readable form c time of filing/furnishing ☐ contained in the international application as filed ☐ filed together with the international application in computer readable 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
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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 19 with respect to Industrial Applicability

because

- ☒ the said international application, or the said claims Nos 19 with respect to Industrial Applicability relate to the following subject matter which does not require an international preliminary examination (*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
- ☐ no international search report has been established for the whole application or for said claims Nos
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that
- the written form ☐ has not been furnished
- ☐ does not comply with the standard
- the computer readable form ☐ has not been furnished
- ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions
- ☐ See separate sheet for further details

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US2005/023798

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, 4-8, 9-18
	No	Claims	1, 3, 7, 8, 19
Inventive step (IS)	Yes	Claims	
	No	Claims	1-19
Industrial applicability (IA)	Yes	Claims	1-18
	No	Claims	

2 Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 19 relates 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

Reasoned statement with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement

1) Reference is made to the following document/s/

- D1 LUUKKAINEN T ET AL "INHIBITION OF FOLLICULOGENESIS AND OVULATION BY THE ANTIPROGESTERONE RU-486" FERTILITY AND STERILITY, ELSEVIER SCIENCE INC, NEW YORK, NY, US, vol 49, no 6, 1988, pages 961-963, XP002189879 ISSN 0015-0282
- D2 DANIELSSON K GEMZELL ET AL "Effect of low daily doses of mifepristone on ovarian function and endometrial development" HUMAN REPRODUCTION (OXFORD), vol 12, no 1, 1997, pages 124-131, XP002350882 ISSN 0268-1161
- D3 CROXATTO H B ET AL "Effects of long-term low-dose mifepristone on reproductive function in women" HUMAN REPRODUCTION (OXFORD), vol 13 no 4, April 1998 (1998-04), pages 793-798, XP002350883 ISSN 0268-1161
- D4 REEL JERRY R ET AL "Antiovulatory and postcoital antifertility activity of the antiprogesterin CDB-2914 when administered as single, multiple, or continuous doses to rats" CONTRACEPTION, vol 58, no 2, August 1998 (1998-08), pages 129-136, XP002350884 ISSN 0010-7824
- D5 BROWN AUDREY ET AL "Daily low-dose mifepristone has contraceptive potential by suppressing ovulation and menstruation. A double-blind randomized control trial of 2 and 5 mg per day for 120 days" JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, vol 87, no 1, January

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

International application No

PCT/US2005/023798

2002 (2002-01), pages 63-70, XP002350885 ISSN 0021-972X
D6 US 2002/049204 A1 (ZHANG PUWEN ET AL) 25 April 2002 (2002-04-25)
D7 WO 00/86556 A (AMERICAN HOME PRODUCTS CORPORATION, LIGAND
PHARMACEUTICALS, INC, FENSO) 9 November 2000 (2000-11-09)

- 2) The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 3, 7, 8, 19 is not new in the sense of Article 33(2) PCT

Document D1 discloses the use of mifepristone as contraceptive which is administered for a first phase of 21 days followed by a second phase where no active is given. The fact that a placebo is given (feature b) simply means that something is given, which is not deemed a distinctive addition.

Therefore the subject matter of claims 1, 3, 7, 8, 19 is not new.

- 3) The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2, 4-6, 9-18 does not involve an inventive step in the sense of Article 33(3) PCT.

Document D5 discloses that a dosage of 2 and 5 mg of mifepristone resulted in a low occurrence of ovulations in women. According to the applicant, these low ovulation rates are comparable to those of some standard oral contraceptives. Since standard oral contraceptives are given in a 21 day cycle, the applicant expected that PR agonists could also be administered in a similar regimen.

Additionally, document D5 discloses a high occurrence of amenorrhea depending on the dosage. The applicant now concludes that administration PR agonists in a 21 day cycle avoids amenorrhea (see p. 1 last paragraph to page 2 first paragraph).

The same theoretic considerations are to be made by the normal skilled worker. It has to be noted that no experimental data were present at the filing date which underline these theories.

Therefore, these considerations are obvious.

The following has to be added:

It appears that the problem underlying the present application (avoidance of

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

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amenorrhea) is not solved over the whole scope of the claims

Document D2 discloses that menstrual bleed started about 15-20 days after the final treatment (in those cases where amenorrhea was reported) Document D3 reported a menstrual bleed within 3 weeks after stopping the treatment Therefore it is unlikely that the contraceptive regimen as defined resulted in a regular menses within 7 days or in even 1 day after the administration of the PR antagonist

Moreover, document D2 discloses that 0.1 or 0.5 mg of mifepristone did not disturb the normal menstrual cycle rhythm Thus from D2 or D5 it is clear that the problem of amenorrhea only existed for specific daily dosages

Document D4 discloses that a daily dosage of 0.5 mg of mifepristone was not an effective contraceptive Document D3 discloses that during administration of 1 mg mifepristone 14 of 21 women ovulated

Taking all these teachings together, it is clear that the daily dosage is essential for the solution of the problem This feature, however, is not reflected within the claims Therefore the problem is not solved