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**A B O G A D O S**

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2691/PCT

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO**  
**DIVISION DE NUEVAS CREACIONES**

E. S. D.

Radicación : 04065237 00000002 Folios: 7  
Fecha (PMB): 2004-12-28 16:33:43

Re: Expediente No. 04.065.237

Trmite : 011 PCT-PATENT 379 CASE NACT 379 COMA FREN  
Desendencia: 2004 DIVISION DE NUEVAS CREACIONES

Solicitud de patente a nombre de  
The Procter & Gamble Company

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la carrera 11 A No. 94-76, of. 305, obrando como apoderada de la sociedad The Procter & Gamble Company, domiciliada en Cincinnati, Ohio, Estados Unidos de América, solicitante de la patente de la referencia, atentamente me permito presentar copia del examen preliminar internacional junto con su traducción al español.

Señor Superintendente,

  
JIMENA ESCOBAR URIBE  
C.C.39.779.452 de Usaquén  
T.P. 68228

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**TRATAD DE COOPERACION EN MATERIA DE PATENTES**  
**PCT**

**INFORME EXAMEN PRELIMINAR INTERNACIONAL**  
**(PCT artículo 36 y regla 70)**

|                                                                                            |                                                                                                                 |                                                |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Referencia del solicitante o agente<br>8847M2/CA                                           | Ver notificación de la transmisión del examen preliminar Internacional (formato PCT/IPEA/416)<br>PARA PROSEGUIR |                                                |
| No. Solicitud Internacional<br>PCT/US03/01454                                              | Fecha de presentación internacional (día/mes/año)<br>16.01.2003                                                 | Fecha de prioridad (día/mes/año)<br>16.01.2002 |
| Clasificación Internacional de Patentes (IPC) o clasificación nacional e IPC<br>C07K14/575 |                                                                                                                 |                                                |
| Solicitante<br>The Procter & Gamble Company                                                |                                                                                                                 |                                                |

1. Este examen preliminar internacional ha sido preparado por esta Autoridad encargada del Examen Preliminar Internacional y es transmitida al solicitante de acuerdo con el artículo 36.

2. Este INFORME consiste de un total de 2 páginas, incluyendo esta hoja.

\_\_\_ Este informe también está acompañado por ANEXOS, esto es hojas de la descripción, reivindicaciones y/o dibujos, los cuales han sido modificados y son la base para este Informe y/o hojas que contienen rectificaciones presentadas ante esta Autoridad (ver Regla 70.16 y Sección 607 de las Instrucciones Administrativas bajo el PCT).

Estos anexos consisten en un total de \_\_\_ hojas.

3. Este Informe contiene indicaciones que se relacionan con los siguientes puntos:

- I. ☒ Base del Informe
- II. ☐ Prioridad
- III. ☐ El no-establecimiento de opinión en relación con la novedad, nivel inventivo y aplicación industrial
- IV. ☐ Falta de unidad de invención
- V. ☒ Declaración motivada bajo el Art. 35(2) con relación a la novedad, nivel inventivo o aplicación industrial; citaciones y explicaciones que soportan dicha declaración
- VI. ☐ Ciertos documentos citados
- VII. ☐ Ciertos defectos en la solicitud internacional
- VIII. ☐ Ciertas observaciones en la solicitud internacional

|                                                                                                                                                                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Fecha de presentación de la demanda                                                                                                                                                                                                                | Fecha en que se completó este Informe                                       |
| Nombre y dirección de la autoridad encargada del examen preliminar Internacional IPEA/US:<br><br>Mail Stop PCT, Attn: IPEA/US<br>Comisionado para las patentes<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Oficial autorizado<br><br>Jeffrey E. Russel<br><br>Teléfono: +(571)272 1600 |

**Nivel Inventivo**

**SI:** Reivindicaciones 16, 18 y 19

**NO:** Reivindicaciones 1-15, 17, 20 y 21

Aplicación Industrial

SI: Reivindicaciones 1-21

NO: Reivindicaciones

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## 2. CITACIONES Y EXPLICACIONES

Las reivindicaciones 1-15 y 20 no tienen nivel inventivo bajo el artículo 33 (2) del PCT ya que son anticipadas por la Universidad de California. La Universidad de California enseña que agonistas CRF-R2 son terapéuticamente útiles como agentes anti-inflamatorios. Ver por ejemplo página 8, página 11, página 12 y tabla IB. En vista de la similitud en cuanto a la estructura y la función entre los antagonistas de la Universidad de California y los del solicitante específicamente ejemplificados como péptidos, los originales son variantes del posterior. Nótese que el solicitante amplía la definición de variantes en las páginas 17-18 de la descripción.

La reivindicación 21 no tiene nivel inventivo bajo el artículo 33(2) del PCT porque es obvio respecto a la Univ de California. La solicitud de la Universidad de California no enseña los antagonistas de la forma de un kit con instrucciones para uso. Ha venido siendo obvio para una persona ordinariamente versada en la materia al momento en que la invención del solicitante fue hecha para empacar los antagonistas de Universidad de California en la forma de un kit, que incluye instrucciones de uso, porque dicha forma de kit es standard para agentes terapéuticos y tiene los beneficios de mejorar el almacenamiento, transporte, medida y administración.

Las reivindicaciones 16, 18 y 19 cumplen con el criterio establecido en el artículo 33(2)-(3), porque el arte anterior no enseña o siquiera sugiere péptidos que tienen secuencias de aminoácidos como los contenidos en la presente reivindicación 16. Además, con relación a la presente reivindicación 18 porque los agonistas de la Univ de California son requeridos para comprender un amino ácido D. La Univ de California no sugiere ácidos nucleicos que codifiquen dichos péptidos. Finalmente, en relación con la presente reivindicación 19, Univ de California no provee ninguna motivación para producir anticuerpos que son específicos para revelar agonistas.

Las reivindicaciones 1-21 cumplen con el criterio establecido en el artículo 33(4) del PCT y por lo tanto tienen aplicación industrial por dicha materia reivindicada ya que puede ser usada industrialmente. La invención reivindicada se espera que tenga aplicación industrial en el tratamiento de los desordenes del factor de liberación del receptor de corticotropin modulado.

## PATENT COOPERATION TREATY

RECEIVED

AUG 30 2004

P & G Patent Division  
International ITCFrom the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo  
T. DAVID REED  
THE PROCTER & GAMBLE COMPANY  
6110 CENTER HILL ROAD  
CINCINNATI, OH 45224H.R.: Grogan  
C.S.: Liou  
I.E.: Anker & Liek

PCT

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

H. Grogan, Jr. Dogni, Jr.

Date of Mailing  
(day/month/year)

26 AUG 2004

Applicant's or agent's file reference

3347M2/CA

## IMPORTANT NOTIFICATION

International application No.

PCT/US03/01454

International filing date (day/month/year)

16 January 2003 (16.01.2003)

Priority date (day/month/year)

16 January 2002 (16.01.2002)

Applicant

THE PROCTER &amp; GAMBLE COMPANY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Form PCT/IPEA 416 (July 1992)

Authorized officer

Jeffrey E. Russel

Telephone No. (571) 322-1600

Della Collins for

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/01454

## 1. Basis of the report

## 1 With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
 pages 1-55 as originally filed  
 pages NONE filed with the demand  
 pages NONE filed with the letter of \_\_\_\_\_
- ☒ the claims:  
 pages 56-58 as originally filed  
 pages NONE as amended (together with any statement) under Article 19  
 pages NONE filed with the demand  
 pages NONE filed with the letter of \_\_\_\_\_
- ☐ the drawings  
 pages NONE as originally filed  
 pages NONE filed with the demand  
 pages NONE filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description.  
 pages 1-242 as originally filed  
 pages NONE filed with the demand  
 pages NONE filed with the letter of \_\_\_\_\_

## 2 With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3 With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4 ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/014547  
451

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. STATEMENT

|                               |                             |     |
|-------------------------------|-----------------------------|-----|
| Novelty (N)                   | Claims 16, 18, 19, and 21   | YES |
|                               | Claims 1-15, 17, and 20     | NO  |
| Inventive Step (IS)           | Claims 16, 18, and 19       | YES |
|                               | Claims 1-15, 17, 20, and 21 | NO  |
| Industrial Applicability (IA) | Claims 1-21                 | YES |
|                               | Claims NONE                 | NO  |

## 2. CITATIONS AND EXPLANATIONS

Claims 1-15, 17, and 20 lack novelty under PCT Article 33(2) as being anticipated by Univ California. Univ California teaches CRF-R2 agonists which are used therapeutically as anti-inflammatory agents. See, e.g., page 8; page 11; page 12; and Table 1B. In view of the similarity in structure and function between the agonists of Univ California and Applicant's specifically exemplified peptides, the former are deemed to be variants of the latter. Note Applicant's relatively broad definition of "variants" at pages 17-18 of the disclosure.

Claim 21 lacks an inventive step under PCT Article 33(3) as being obvious over Univ California. Application of Univ California is the same as in the above paragraph. Univ California does not teach its agonists in the form of a kit with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to package the agonists of Univ California in the form of a kit including instructions of use, because such a kit form is standard for therapeutic agents and has the benefits of improved storage, transportation, measurement, and administration.

Claims 16, 18, and 19 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest peptides having the amino acid sequences recited in instant claim 16. Further, with respect to instant claim 18, because the agonists of Univ California are required to comprise a D-amino acid, Univ California does not suggest nucleic acids which encode such peptides. Finally, with respect to instant claim 19, Univ California does not provide any motivation to produce antibodies which are specific for the disclosed agonists.

Claims 1-21 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry. The claimed invention would have been expected to have industrial applicability in the treatment of corticotropin releasing factor 2 receptor modulated disorders.

----- NEW CITATIONS -----

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. STATEMENT

|                               |                                    |     |
|-------------------------------|------------------------------------|-----|
| Novelty (N)                   | Claims <u>16, 18, 19, and 21</u>   | YES |
|                               | Claims <u>1-15, 17, and 20</u>     | NO  |
| Inventive Step (IS)           | Claims <u>16, 18, and 19</u>       | YES |
|                               | Claims <u>1-15, 17, 20, and 21</u> | NO  |
| Industrial Applicability (IA) | Claims <u>1-21</u>                 | YES |
|                               | Claims <u>NONE</u>                 | NO  |

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----- NEW CITATIONS -----