

ESCOBAR - URIBE ASOCIADOS

A B O G A D O S

Carrera 11A No. 94-76 Of. 305 - P.O. Box 94948, Santafé de Bogotá, Colombia, S.A.
Tel.: (571) 6162051 - 6162061 - 6161859 - 6161869
Fax: (571) 6161889

2395/P

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

Re: Expediente No. 00.090.144
Solicitud de Patente en nombre de
McNeil-PPC, Inc

SUPERINDUSTRIA Y COMERCIO
Radicación: 00090144 00000001 Folios: 17
Fecha (AMD): 2001-02-16 16:04:07
Trámite: 002 PATENTES D 1 REGISTRO/ 329 COMPLEMEN
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la carrera 11 A No. 94-76 Of. 305, obrando como apoderada de la sociedad McNeil-PPC, Inc., solicitante de la patente de la referencia anexo al presente memorial los siguientes documentos:

Copia certificada de la solicitud de Patente Número 09/448,988 presentada en los Estados Unidos de América el día 24 de noviembre de 1999, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio.

A este mismo respecto, debe tenerse en cuenta que en la primera página de la copia en mención de la Oficina de Patentes correspondiente certificó la fecha de presentación de esa solicitud, cumpliéndose de esta forma todos y cada uno de los requisitos establecidos en el inciso segundo del artículo 10 de la decisión 486 de la Comisión de la Comunidad Andina.

En relación con la copia certificada de la prioridad reivindicada en esta solicitud que fue presentada el día 6 de noviembre de 2000 en los Estados Unidos de América, me permito manifestar que mi mandante desiste reivindicar dicha prioridad y, por lo tanto, solicita a ese despacho continuar con el trámite de la presente solicitud de patente teniendo únicamente como prioridad reivindicada aquella cuya copia certificada se anexa al presente memorial, es decir la patente número 09/448,988 presentada en los Estados Unidos de América el día 24 de noviembre de 1999.

Señor Superintendente,



JIMENA ESCOBAR URIBE
C.C.39.779.452 de usaquén
T.P. 68228
Cód. 5376

**ESTADOS UNIDOS DE AMERICA
A TODOS AQUELLOS A QUIENES EL PRESENTE
LLEGUE:**

**DEPARTAMENTO DE COMERCIO DE LOS ESTADOS
UNIDOS
Oficina de Patentes y Marcas de los Estados Unidos**

Diciembre 6, 2000

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 09/448,988

Fecha de Presentación: Noviembre 24, 1999

**Por la autoridad del
Comisionado de Patentes y Marcas**

**(fdo) P.R. GRANT
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los
Estados Unidos de América**

REIVINDICACIONES

2a
26

- 1.- Un método para calmar o tratar la fotofobia asociada con migraña que comprende:
proveer una cantidad efectiva de acetaminofén como único ingrediente farmacéuticamente efectivo.
- 2.- El método de conformidad con la reivindicación 1 en donde la cantidad de acetaminofén es de aproximadamente 650 a aproximadamente 1300 miligramos por dosificación.
- 3.- El método de conformidad con la reivindicación 1 en donde la cantidad de acetaminofén es de aproximadamente 800 a aproximadamente 1000 miligramos por dosis.
- 4.- Un método para calmar o tratar la fonofobia asociada con migraña, que comprende:
proveer una cantidad efectiva de acetaminofén como único ingrediente farmacéuticamente activo.
- 5.- El método de conformidad con la reivindicación 4 en donde la cantidad de acetaminofén es de aproximadamente 650 a aproximadamente 1300 miligramos por dosis.

6.- El método de conformidad con la reivindicación 4 en donde la cantidad de acetaminofén es de aproximadamente 800 a aproximadamente 1000 miligramos por dosis.

30
27

34
28

PA 338031



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 06, 2000

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 09/448,988

FILING DATE: November 24, 1999



**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**

P. R. GRANT

Certifying Officer

295

Please type a plus sign (+) inside this box ☒

**UTILITY
PATENT APPLICATION
TRANSMITTAL**

Attorney Docket No.

MCP-239

First Named Inventor or Application Identifier

Joseph R. Codispoti

Express Mail Label No.

EL327261688US

APPLICATION ELEMENTS

See MPEP Chapter 800 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form (attached hereto in duplicate)

2. ☒ Specification [Total Pages 6]

(Preferred arrangement set forth below)

- Descriptive Title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R&D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. ☒ Drawing(s) (35 USC 113) [Total Sheets 2]

4. Oath or Declaration

- a. ☐ Newly executed (original or copy)
- b. ☒ Unexecuted original
- c. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional check boxes 5 and 16)
- l. ☐ Deletion of Inventor(s)
Signed statement attached deleting
inventor(s) named in the prior application,
see 37 CFR 1.63(d)(2) and 1.33(b).

5. ☐

Incorporation by Reference

(useable if Box 4c is checked)

The entire disclosure of the prior application, from
which a copy of the oath or declaration is supplied
under Box 4c, is considered as being part of the
disclosure of the accompanying application and is
hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)

7. Nucleotide and/or Amino Acid Sequence
Submission (if applicable, all necessary)

- a. ☐ Computer Readable Copy
- b. ☐ Paper Copy (identical to computer copy)
- c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

- 8. ☐ Assignment Papers (cover sheet &
document(s))
- 9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐ Power of Attorney
- 10. ☐ English Translation Document (if applicable)
- 11. ☐ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
- 12. ☐ Preliminary Amendment
- 13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
- 14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)

15. ☐ Other:

16. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:

Amend the specification by inserting before the first line: - This is a ☐ Continuation ☐ Divisional
☐ Continuation-in-Part (CIP) of prior application No.: filed

17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label

or ☒ Correspondence Address below

Name: Audley A. Ciamporero, Jr., Esq.

Address: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003 USA

19. TELEPHONE CONTACT

Please direct all telephone calls or telefaxes to Joseph F. Leightner at:

Telephone: (732) 524-1214 Fax: (732) 524-2808

19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME

Joseph F. Leightner

Reg. No. 34,209

SIGNATURE

DATE

November 24, 1999

VIA EXPRESS MAIL NO. EL327261688US
MAILED NOVEMBER 24, 1999

33
30

METHOD FOR TREATING MIGRAINE SYMPTOMS

Field of the Invention

5 The present invention relates to the treatment of
migraines symptoms by the administration of an effective
amount of acetaminophen, more specifically the present
invention relates to the treatment of phonophobia and
photophobia with acetaminophen.

10 Background of the Invention

Migraine provides a wide variation of pain and symptoms,
and associated disorders with those who suffer from the
disease. Included among these symptoms are nausea, headache,
moderate to severe pain, as well as incapacitating pain and
15 total disability in a percentage of patients. Some patients
also recite more specific symptoms such as photophobia,
painful sensitivity to light; or phonophobia, painful
sensitivity to sound.

20 Treatment of migraine pain includes both prescription and
non-prescription or over-the-counter medication. Among the
over-counter medication that is currently available is a
combination of acetaminophen/aspirin/caffeine, as set forth in
US Patent 5,972,916, the contents hereby incorporated by
25 reference as set forth herein in its entirety. The
combination of active ingredients suffers from the drawback
that some of the actives might cause undesired side effects.
For example, it is well know that aspirin can cause stomach
irritation and caffeine can cause anxiety and sleeplessness.

30

Therefore there is a continuing need for treatment of
migraines, as well as treatment alternatives to specific
migraine symptoms.

35 Summary of the Invention

The present invention provides a method for treating
photophobia and phonophobia associated with a migraine attack

MCP-239

VIA EXPRESS MAIL NO. EL327281688US
1 - MAILED NOVEMBER 24, 1999

09449988-112499

by providing an effective amount of acetaminophen. The present invention relies on the action of a single active ingredient, i.e., acetaminophen. The present invention contemplates the use of additional ingredients, such as
5 flavors, binders and excipients.

Description of the Drawings

Figure 1 depicts the percentage of subjects with reduced photophobia over time after treatment with acetaminophen.

10 Figure 2 depicts the percentage of subjects with reduced phonophobia over time over time after treatment with acetaminophen.

Detailed Description of the Invention

15

Acetaminophen is a well known analgesic material which has analgesic and antipyretic properties. It is commercially available in various forms for many years.

20

The present invention is preferably administered as an oral dose as an effective dose to alleviate the photophobia and phonophobia symptoms, which comprises from about 650 to about 1300 milligrams of acetaminophen per dose; preferably from 800 to about 1200 and most preferably from about 900 to
25 about 1000 milligrams per dose. Typically doses are taken every four to six hours, but care should be taken to avoid the daily maximum recommended dosage of acetaminophen of 4000 milligrams per day.

30

Suitable dosage forms include solids or liquids. Solid forms include pills capsules, powders, sachets and the like. Suitable liquids include suspensions, solutions, emulsions and the like.

35

The acetaminophen may be admixed with various pharmaceutically-acceptable excipients and other ingredients including but not limited to diluents, granulating,

disintegrating agents, binding agents, lubricants and the like. Examples of these various ingredients are set forth in US Patent 5,660,860, the contents hereby incorporated by reference as if set forth in its entirety.

The present invention as set forth in the following examples are meant to exemplify the various aspects of carrying out the present invention and are not intended to limit the invention in any way.

Example 1

Subjects suffering from migraine photophobia due to a migraine were either given a placebo or treated with 1000 milligrams of acetaminophen. One hundred seventy-five (175) subjects were treated with acetaminophen in tablet form, and one hundred fifty-nine subjects were given placebos. Periodic assessments of their photophobia were made and the results are presented below.

Percentage (Number) of Subjects with Photophobia Severity Reduced to Zero by Time-Intent-to-Treat

		Assessment Timepoints (Hours)							
Treatment		0.5	1	1.5	2	3	4	5	6
APAP 1000 mg (N=175)		2.3 (4)	5.7 (10)	13.7 (24)	19.4 (34)	31.4 (55)	36.0 (63)	39.4 (69)	42.3 (74)
Placebo (N=159)		3.1 (5)	5.0 (8)	11.9 (19)	13.2 (21)	14.5 (23)	21.4 (34)	25.8 (41)	25.8 (41)
p-Value		0.127							0.002

The results are also provided in Figure 1. The results indicate that at time of two hours or longer the treatment of photophobia with acetaminophen was effective in treating photophobia and statistically significant.

0944888-112498

26
32

Example 2

Subjects suffering from migraine phonophobia due to a migraine were either given a placebo or treated with 1000 milligrams of acetaminophen in tablet form. One hundred sixty-two (162) subjects were treated with acetaminophen, and one hundred fifty-seven (157) subjects were given placebos. Periodic assessments of their photophobia were made and the results are presented below.

10

Percentage (Number) of Subjects with Phonophobia Severity Reduced to Zero by Time-Intent-to-Treat

Treatment	Assessment Timepoints (Hours)							
	0.5	1	1.5	2	3	4	5	6
APAP 1000 mg (N=162)	3.1 (5)	8.0 (13)	16.0 (26)	22.8 (37)	30.9 (50)	37.0 (60)	40.7 (66)	42.6 (69)
Placebo (N=157)	3.2 (5)	5.7 (9)	10.2 (16)	12.7 (20)	17.2 (27)	21.7 (34)	25.5 (40)	26.1 (41)
p-Value	0.018				0.002			

The results are also provided in Figure 2. The results indicate that at time of two hours or longer the treatment of phonophobia with acetaminophen was effective in treating phonophobia and statistically significant.

664211-88684460

I claim:

1. A method for mitigating or treating photophobia associated with migraine comprising:

5 providing an effective amount of acetaminophen as the sole pharmaceutically effective ingredient.

2. The method of claim 1 wherein the amount of acetaminophen is from about 650 to about 1300 milligrams
10 per dosage.

3. The method of claim 1 wherein the amount of acetaminophen is from about 800 to about 1000 milligrams per dose.
15

4. A method for mitigating or treating phonophobia associated with migraines comprising:

providing an effective amount of acetaminophen as the sole pharmaceutically active ingredient.
20

5. The method of claim 4 wherein the amount of acetaminophen is from about 650 to about 1300 milligrams per dosage.

25 6. The method of claim 4 wherein the amount of acetaminophen is from about 800 to about 1000 milligrams per dose.

09448988-112499

35

ABSTRACT OF THE INVENTION

The present invention provides a method for treating
the photophobia and phonophobia symptoms of migraine
5 attacks with an effective amount of acetaminophen.

09448988.112499

39
36

DOCKET NO. MCP-239

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD FOR TREATING MIGRAINE SYMPTOMS, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

VIA EXPRESS MAIL NO. EL327261688US
- MAILED NOVEMBER 24, 1999 -

0944888-11243
664211-88684460

40
37

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number)

(Filing Date)

(Application Number)

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No. Filing Date Status

Application Serial No. Filing Date Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporcaro, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Michael Stark (Reg. #32,495), and Joseph F. Leightner (Reg. #34,209) One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

Address all telephone calls to Joseph F. Leightner at telephone no. (732) 524-1214.

09448988-112499

Address all correspondence to Audley A. Ciamporzero, Jr., One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's Signature:
Full Name of Sole
or First Inventor

Joseph R. Codispoti

Date: _____

Citizenship: U.S.A.

Residence: 13001 Worthington Road, Philadelphia, PA 19116

Post Office Address: Same as above

Inventor's Signature:
Full Name of Second Joint
Inventor, If Any

Date: _____

Citizenship:

Residence:

Post Office Address:

Inventor's Signature:
Full Name of Third Joint
Inventor, If Any

Date: _____

Citizenship:

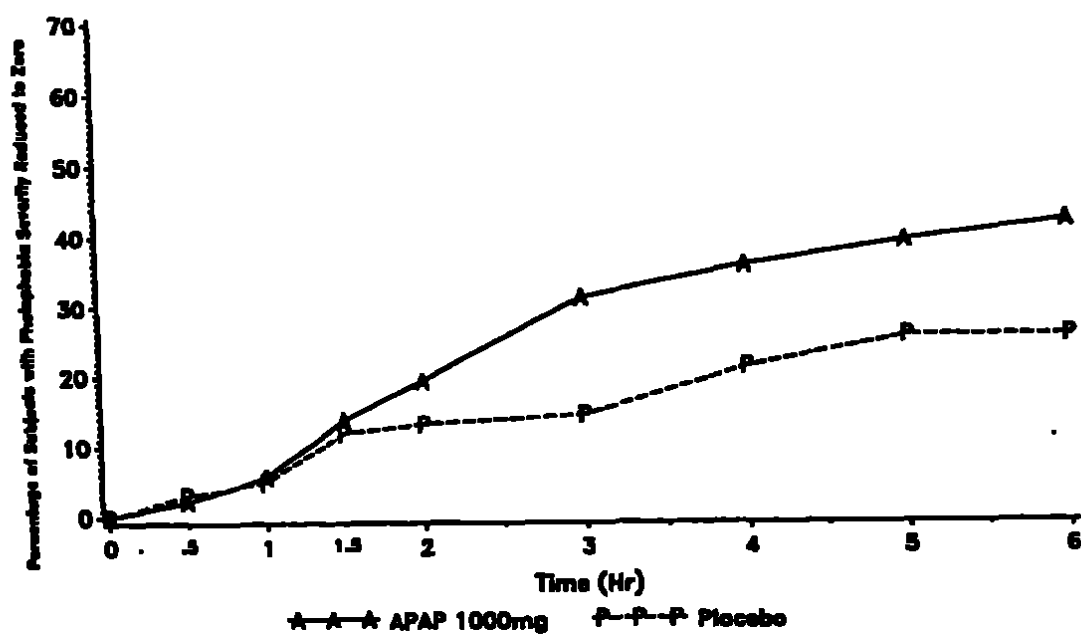
Residence:

Post Office Address:

(Supply similar information and signature for fourth and subsequent joint inventors.)

044884460

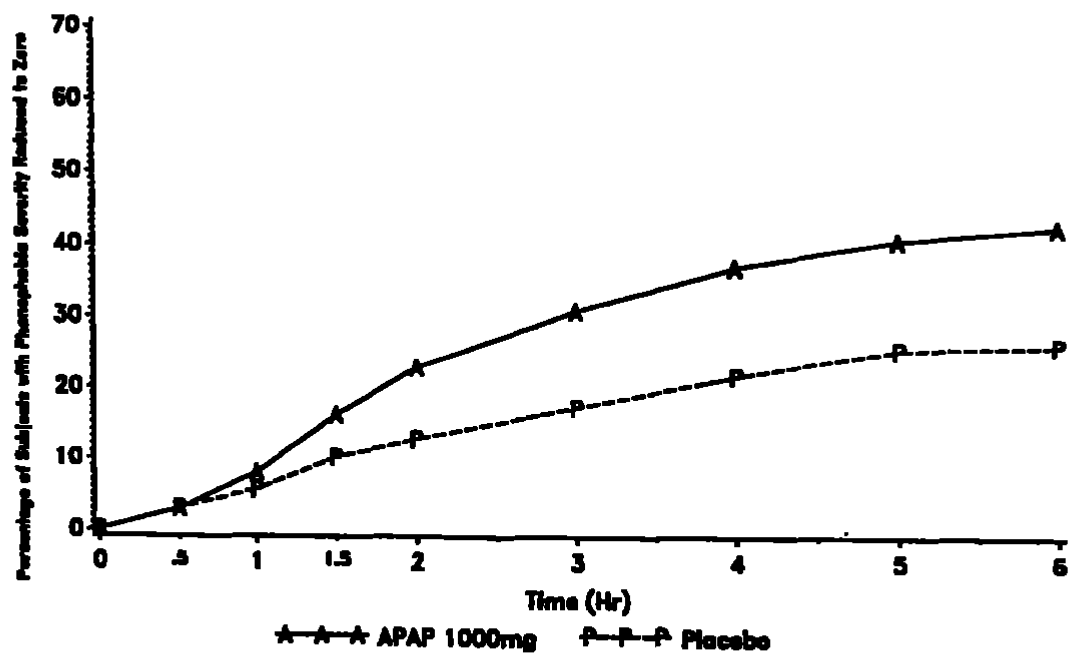
Figure 1 Percentage of Subjects with Photophobia Severity Reduced to Zero by Time



0444998884460

43-1
40

Figure 2 Percentage of Subjects with Phosophobia Severity Reduced to Zero by Time



05448988.11460